IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

The University of Chicago Medical Center d/b/a University of Chicago Hospitals & Clinics, Plaintiff, vs. Michael O. Leavitt, Secretary U.S. Department of Health and Human Services, Defendant.	Case No. 1:07-cv-07016 Judge Wayne R. Andersen

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION AND STATEMENT OF THE CASE

This case presents the issue of whether the Secretary of Health and Human Services (the "Secretary") must include residents' research time when calculating Medicare payments to the University of Chicago Medical Center ("Plaintiff" or "Provider") for its indirect costs of medical education. Plaintiff is an academic medical center that provides training to medical school graduates who are enrolled in approved medical residency programs. As a teaching hospital that furnishes services to Medicare patients, Plaintiff expects and is entitled to receive Medicare payments for both its indirect and direct costs of graduate medical education. 42 U.S.C. §§ 1395ww(d)(5)(B), 1395ww(h); 42 C.F.R. §§ 412.105, 413.86.[1] These payments depend, in part, on Plaintiff's number of full-time equivalent residents ("FTEs") that train at Plaintiff during any given fiscal year. *See* 42 U.S.C. §§ 1395ww(d)(5)(B), 1395ww(h); 42 C.F.R. §§ 412.105(f), 413.86(f).

In August 2007, the Provider Reimbursement Review Board ("PRRB" or "Board"), the administrative body created by statute to decide Medicare reimbursement disputes, issued a thorough and well-reasoned decision unanimously holding that Plaintiff is entitled to include research time in its count of indirect medical education ("IME") FTEs for its fiscal year ending June 30, 1996 ("FY 1996"). Accordingly, the PRRB ordered the Secretary's contractor, the Medicare fiscal intermediary, to add time spent in research to Plaintiff's IME FTE count.[2] In October 2007, however, the Secretary, acting through his designee, the Administrator of the Centers for Medicare and Medicaid Services ("CMS"), reversed the Board. (Administrative Record ("AR") at 2-14.) The Secretary's determination was based upon his view that these FTEs are not includable because the residents in question were engaged in research that did not involve direct care of individual patients. (AR at 10.)

The Secretary has excluded research time from Plaintiff's IME FTE count in direct contravention of three federal district court decisions. *R.I. Hosp. v. Leavitt*, 501 F. Supp. 2d 283 (D.R.I. 2007); *Univ. Med. Ctr. v. Leavitt*, No. 05-CV-495 TUCJMR, 2007 WL 891195 (D. Ariz.

[1] The Medicare direct graduate medical education regulation at 42 C.F.R. § 413.86 was redesignated as 42 C.F.R. § 413.78. 69 Fed. Reg. 48,916 (Aug. 11, 2004). This memorandum refers to the 1995 regulation at Section 413.86 because that was the regulation in effect for Plaintiff's fiscal year 1996.

[2] In administering the Medicare program, the Secretary contracts with outside organizations, usually insurance companies, to perform certain audit, administrative, and payment functions with respect to providers of services. These organizations are known as "fiscal intermediaries." 42 U.S.C. § 1395h.

Mar. 21, 2007); *Riverside Methodist Hosp. v. Thompson*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341 (S.D. Ohio 2003) (AR at 1035-43). Each court determined that the Secretary's IME regulation unambiguously requires the inclusion of research time in the FTE count. *R.I. Hosp.*, 501 F. Supp. 2d at 291; *Univ. Med. Ctr.*, 2007 WL 891195 at *2; *Riverside*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341, at 805,024 (AR at 1043). The arguments that the Secretary presented before those courts were indistinguishable from his justifications for excluding research time from Plaintiff's IME FTEs. Thus, the Secretary now attempts a fourth bite at the apple. The Secretary's arguments, however, are no more availing now than they were before.

As this memorandum and the cases show, the PRRB correctly ruled that resident research time must be included in Plaintiff's 1996 Medicare IME payment calculation, and Plaintiff is entitled to summary judgment as a matter of law. The Secretary's policy violates the plain language of the statutory provision establishing the IME payment and deprives Plaintiff of the Medicare payment to which it is legally entitled. The Secretary's policy contravenes the congressional mandate that teaching hospitals be reimbursed for all their indirect costs of medical education. The Secretary's policy is contrary to the plain meaning of the IME regulation that was in effect for FY 1996 and to his longstanding practice of including research time in the IME FTE count. The Secretary's exclusion of research time for FY 1996 is an impermissible retroactive application of a 2001 change to the regulation. Finally, the Secretary's conclusion that the residents in question were not training in allowable portions of the hospital is *ultra vires* and not supported by substantial evidence. Accordingly, Plaintiff contends that the Secretary's exclusion of these FTEs from the calculation of Plaintiff's IME payment for FY 1996 is arbitrary, capricious, an abuse of discretion, not supported by substantial evidence, and must be reversed.

II. LEGAL BACKGROUND

A. General Overview of the IME Statute and Regulation

The Medicare statute requires the Secretary to reimburse teaching hospitals, such as Plaintiff, for the indirect costs of graduate medical education: "[t]he Secretary shall provide for an additional payment amount for . . . hospitals [subject to the prospective payment system] with indirect costs of medical education, in an amount computed in the same manner as the

adjustment for such costs under regulations (in effect as of January 1, 1983) . . . ." 42 U.S.C. § 1395ww(d)(5)(B). The statute then sets forth an IME calculation to implement this principle:

> [{1+(R/B)}n-1] x C = "IME Adjustment Factor"
>
> Where: R = Number of Resident FTEs
>
> B = Hospital's Beds
>
> n = .405 (Measurement Factor for Teaching Activity)
>
> C = Statutory Adjustment Factor.

Id. This dispute involves the proper determination of the variable "R," i.e., the number of FTEs.

For fiscal year 1996, the year at issue here, the following regulation governed the counting of residents for purposes of the IME payment adjustment:

> (1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent residents for the purpose of determining the indirect medical education adjustment is determined as follows:
> (i) The resident must be enrolled in an approved teaching program. . . .
> (ii) In order to be counted, the resident must be assigned to one of the following areas:
> (A) The portion of the hospital subject to the prospective payment system.
> (B) The outpatient department of the hospital.

42 C.F.R. § 412.105(g) (1995).[3]

Because the statute requires the IME adjustment to be calculated in the "same manner" as it was in 1983, and because the Secretary asserts that his IME research policy merely reflects his prior interpretation of the IME regulation, it is necessary to address the history of these two provisions in some detail.

B. Origin of the Indirect Medical Education Adjustment Factor

1. *Early Medicare Payments for Medical Education*

The Medicare program, established at Title XVIII of the Social Security Act (the "Medicare statute"), is a public health insurance program that furnishes health benefits to individuals who are at least 65 years old, have a qualifying disability, or suffer from end-stage renal disease. 42 U.S.C. § 1395c. Medicare beneficiaries are entitled to have payment made by Medicare on their behalf for, *inter alia*, inpatient and outpatient hospital services provided by a

[3] This regulation was redesignated from 42 C.F.R. § 412.105(g) to § 412.105(f). *See* 62 Fed. Reg. 45,966, 46,029 (Aug. 29, 1997).

hospital participating in the Medicare program as a provider of health care services. 42 U.S.C. §§ 1395d(a), 1395k(a).

In the early years of the program, Medicare reimbursed hospitals based on the "reasonable cost" of hospital services, which included the costs of resident and intern services (collectively, "residents"). 42 U.S.C. § 1395f(b)(1); *see also* 42 C.F.R. § 413.85. Medicare reasonable cost reimbursement rules have always defined the allowable costs of approved medical education programs to include the residents' stipends, the compensation paid by hospitals to teachers, and other indirect overhead costs associated with these programs. *See generally* 42 C.F.R. § 405.421(g) (1983) (AR at 961) (defining allowable costs of approved educational activities, including residency training programs).

2. *Development of the IME Adjustment*

Congress imposed per diem limits on hospitals' allowable inpatient routine costs in Section 223 of the Social Security Amendments of 1972 ("Section 223" limits). In 1979, the Secretary excluded the costs of approved graduate medical education programs from the calculation of the Section 223 limits. 44 Fed. Reg. 31,806 (June 1, 1979). In 1980, however, the Secretary determined that there was still "a high degree of correlation" between a hospital's inpatient routine operating costs and its level of "teaching activity," and, therefore, the Section 223 per diem limits should be adjusted upward to account for higher "indirect" operating costs that statistically correlated with the ratio of residents to beds. 45 Fed. Reg. 21,582, 21,584 (Apr. 1, 1980) (AR at 973-80). The initial adjustment for indirect medical education costs was implemented for 1981 and was based on a hospital's resident FTE count, which was subject to just two exclusions: the count excluded interns and residents who were not physically at the hospital, and the count excluded residents who were not in an approved training program. *Id.* The count did not exclude residents' time spent in research or other educational activities within the scope of an approved program on the hospital premises.

In 1982, Congress passed the Tax Equity and Fiscal Responsibility Act of 1982 ("TEFRA"), which imposed additional limits on hospital operating costs. In implementing the TEFRA limits, the Secretary again included an adjustment to account for the indirect costs of medical education. 47 Fed. Reg. 43,296, 43,310 (Sept. 30, 1982) (AR at 991). For the TEFRA IME adjustment, the Secretary used the same methodology to determine the resident count that

he had used under the Section 223 limits. 47 Fed. Reg. at 43,302 (AR at 987). The TEFRA regulations, including the IME adjustment, were in effect as of January 1, 1983. 47 Fed. Reg. at 43,296 (AR at 982). This methodology did not exclude residents' time spent in research or other educational activities within the scope of an approved program at a hospital. 47 Fed. Reg. at 43,310 (AR at 991). Similarly, the instructions to the hospital cost report in use at that time, the Medicare Provider Reimbursement Manual ("PRM"), and the CMS form for reporting the number of interns and residents at the beginning of the year contained no exclusion for resident time spent in research or other educational activities within the scope of an approved program.[4] *See* PRM, Pub. 15-1, ch. 24 § 1208.2 (AR at 995-96); PRM § 2802G (AR at 1012-13); PRM § 2802, Ex. B (AR at 1016-18).

3. *The Prospective Payment System*

In 1983, Congress enacted the prospective payment system ("PPS") for inpatient hospital services. Under this system, which is still in effect today, the inpatient operating costs of hospitals are reimbursed based on prospectively-determined rates for each patient discharge, rather than on the reasonable operating costs for providing the services. Payments are made to hospitals via lump-sum amounts assigned to specific diagnosis-related groups ("DRGs"), determined by a patient's diagnosis at the time of discharge. *See* Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(e); 42 U.S.C. § 1395ww(d). A hospital caring for a Medicare patient who is assigned a given DRG receives a standard reimbursement amount for that patient (subject to certain geographic and other adjustments), regardless of the actual costs of caring for that patient. *See* 42 U.S.C. § 1395ww(d); 42 C.F.R. pt. 412.

In creating PPS, Congress carved out the costs of training interns and residents from the operating costs of inpatient hospital services that are subject to PPS. 42 U.S.C. § 1395ww(a)(4); *see also* 42 C.F.R. § 405.421 (1985) (AR at 963-64). Congress specifically addressed the need for the PPS to account for the costs associated with medical education by providing for additional compensation to hospitals in the form of both "direct" and "indirect" payments. H.R.

[4] After the close of each fiscal year, a hospital files a Medicare "cost report" with its Medicare fiscal intermediary, which audits the cost report and issues a final determination of the hospital's reimbursement for services furnished to program beneficiaries. *See* 42 U.S.C. §§ 1395h, 1395oo(a)(1)(A)(i); 42 C.F.R. §§ 405.1803(a)(1), 413.20. Among the many items reported on the cost report is the number of FTEs used for calculating the IME payment.

Rep. No. 98-25 at 140-41 (1983) (Conf. Rep.), *reprinted in* 1983 U.S.C.C.A.N. 219, 359 (AR at 1029-30); S. Rep. No. 98-23 at 52-53 (1983), *reprinted in* 1983 U.S.C.C.A.N. 143, 192 (AR at 1032-33). The direct graduate medical education payment ("DGME") is designed, as its name implies, to account for the readily identifiable, direct costs associated with residency programs, such as stipends and fringe benefits for residents. 42 U.S.C. §§ 1395ww(h). Congress intended IME, on the other hand, to reimburse hospitals for the more intangible costs associated with the "education process." H.R. Rep. No. 98-25, at 140 (AR at 1029); *see also* S. Rep. No. 98-23, at 52 (AR at 1032).

4. *The IME Adjustment Under PPS*

The Secretary specifically addressed the need for the PPS to account for "indirect costs of graduate medical education." *Report to Congress Required by the Tax Equity and Fiscal Responsibility Act of 1982* (Dec. 1982), *reprinted in* CCH Rep. No. 374, extra ed. 1983 ("*Report to Congress*"), at 48-49 (AR at 1024-26). In the *Report to Congress*, the Secretary acknowledged that while increased operating costs clearly correlate with the intensity of teaching in an institution, the Secretary did not know which part of these increased costs is caused by residents' instruction and which part is due to other factors, such as the types of patients treated by teaching hospitals: "Although it is not known precisely what part of these higher costs are due to teaching (more tests, more procedures, etc.), and what part is due to other factors (the particular types of patients which a teaching hospital may attract), the Medicare cost reports clearly demonstrate that costs per case are higher in teaching hospitals." *Report to Congress* at 48 (AR at 1025). The Secretary thus acknowledged, even prior to the adoption of the PPS, that teaching hospitals incur higher operating costs and that these allowable operating costs are caused at least in part (if not entirely) by factors, such as the *types of patients* treated by teaching hospitals, that have nothing to do with residents' provision of patient care services.

When it enacted the PPS in 1983, Congress adopted the Secretary's recommendation and incorporated an IME payment adjustment equal to twice the amount of the Secretary's IME adjustment under the Section 223 limits. 42 U.S.C. § 1395ww(d)(5)(B); S. Rep. No. 98-23, at 52 (AR at 1032); *see also* H.R. Rep. No. 98-25, at 140 (AR at 1029). The statute expressly adopts the methodology used by the Secretary to establish and apply the adjustment under TEFRA and the Section 223 limits, except as Congress has modified that adjustment (e.g., through increasing

the amount of the adjustment): "The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed *in the same manner as* the adjustment for such costs under regulations (in effect as of January 1, 1983) . . . except as follows . . . ." 42 U.S.C. § 1395ww(d)(5)(B) (emphasis added). That methodology calculates the IME adjustment based on the intern and resident to bed ratio ("IRB"). H.R. Rep. No. 98-25, at 140 (AR at 1029); S. Rep. No. 98-23, at 52 (AR at 1032).

In creating the IME adjustment, Congress considered several factors that contribute to increased overhead costs at teaching hospitals, e.g., increased demands placed upon staff participating in the education process, the increased number of tests and procedures performed by residents as they learn their medical specialties, and the fact that teaching hospitals may attract sicker patients and provide more specialized services, among other factors. H.R. Rep. No. 98-25, at 140-41 (AR at 1029-30); *see also* S. Rep. No. 98-23, at 52-53 (AR at 1032-33). The IME adjustment was thus created to act as a proxy measure for the level of teaching intensity at a hospital, calculated as a ratio of interns and residents to patient beds. 42 U.S.C. § 1395ww(d)(5)(B); S. Rep. No. 98-23, at 52 (AR at 1032); *see also* H.R. Rep. No. 98-25, at 140 (AR at 1029).

5. *Subsequent Amendments to the IME Adjustment*

Subsequent amendments have expanded upon the original areas that may be included in a teaching hospital's resident count. In 1997, Congress amended the statute to allow hospitals to count residents at non-hospital settings, so long as the residents are engaged in patient-care activities. 42 U.S.C. § 1395ww(d)(5)(B)(iv). The 1997 amendment is the only instance in which Congress has imposed a patient-care requirement on the IME resident count, and that provision applies only with respect to residents' training in a non-hospital setting.

C. Regulatory Background

As explained above, for FY 1996, the IME regulation contained only two requirements for residents to be included in the FTE count: 1) the resident had to "be enrolled in an approved teaching program"; and 2) the resident had to be "assigned" either to the "portion of the hospital subject to the prospective payment system" or to an "outpatient department of the hospital." 42 C.F.R. § 412.105(g) (1995). In 1997, pursuant to the above-noted statutory amendment, the

regulation was amended to include in the FTE count time spent by residents providing direct patient care in non-hospital settings:

> (C) Effective for discharges occurring on or after October 1, 1997, the time spent by a resident in a nonhospital setting in patient care activities under an approved medical residency training program is counted towards the determination of full-time equivalency if the criteria set forth at [the DGME regulations at] § 413.86(f)(1)(iii) [or § 413.86(f)(1)(iv) of this subchapter, as applicable,] are met.

42 C.F.R. § 412.105(f)(1)(ii) (1997).

Prior to October 1, 2001, Medicare regulations permitted that the time spent by interns and residents in training activities could be included in a hospital's resident count for IME purposes, if the training activities were part of an approved educational program. The Secretary had defined approved educational activities to mean formally organized or planned programs of study usually engaged in by providers to enhance the quality of inpatient care in an institution. 42 C.F.R. § 405.421 (1985) (AR at 964).[5] The activities must have been licensed (where required by state law), or approved by a recognized national professional organization. *Id.*

Effective October 1, 2001, the Secretary amended the IME regulation. 66 Fed. Reg. 39,828, 39,933-34 (Aug. 1, 2001). For the first time, the revised regulation restricted the resident count used to calculate a hospital's IME payment by excluding all time spent by residents in research not involving the care of a *particular* patient: "The time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. § 412.105(f)(1)(iii)(B) (2001). The new rule did not define what is included within the scope of "research"; however, in the preamble to the rule, the Secretary indicated that any time spent by a resident that is not associated with the treatment or diagnosis of a particular patient is not countable. 66 Fed. Reg. at 39,897. In proposing the new IME regulation, the Secretary claimed that the change was intended to "reiterate . . . longstanding policy regarding time that residents spend in research and . . . to incorporate this policy in the IME regulations." 66 Fed. Reg. 22,646, 22,699 (May 4, 2001).

[5] This regulation was redesignated to 42 C.F.R. §§ 413.85, 413.90, and 413.94 by 51 Fed. Reg. 34,790 (Sept. 30, 1986).

D. Administrative Appeals

A provider of health care services that is dissatisfied with a final determination of its fiscal intermediary may appeal that determination to the Provider Reimbursement Review Board ("PRRB" or "Board"). 42 U.S.C. § 1395oo(a). A decision of the PRRB is final unless the Secretary "reverses, affirms, or modifies the Board's decision" within 60 days after the provider receives notification of the Board's decision. *Id.* at § 1395oo(f)(1). The Secretary has delegated authority to review Board decisions to the Administrator of CMS, a component agency of the Department of Health and Human Services ("HHS"). 48 Fed. Reg. 45,766, 45,767 (Oct. 7, 1983); *see also* 42 C.F.R. §§ 405.1801(a), 405.1875. CMS regulations also permit the Administrator to remand decisions to the Board. 42 C.F.R. § 405.1875(g). The Administrator may instruct the Board to develop the facts further or consider new issues or certain additional legal authority. *Id.* at § 405.1875(h)(2).

II. FACTUAL BACKGROUND

Plaintiff incorporates by reference its Statement of Material Facts Not in Dispute, which accompanies this Memorandum.

III. STANDARD OF REVIEW

Jurisdiction over this action lies under 42 U.S.C. § 1395oo(f), which provides that the case "shall be tried pursuant to the applicable provisions under chapter 7 of title 5 [the Administrative Procedures Act ("APA")]." The provision of the APA governing the scope of review is 5 U.S.C. § 706, which requires that an administrative decision be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "unsupported by substantial evidence . . . on the record of an agency hearing . . . ." 5 U.S.C. § 706(2)(A),(E).

An agency's construction of the statute it administers is generally governed by *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778 (1984). There are two steps to a court's review under *Chevron*: first, the court must determine whether Congress "has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842-43, 104 S. Ct. at 2781-82. If Congress's intent is clear, then "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* Only if

the statute is ambiguous does the court reach the second step of *Chevron* review, which involves determining whether the agency's interpretation is based upon a permissible construction of the statute. *Id.*

Here, Congress has directly spoken to this issue, given the plain language of 42 U.S.C. § 1395ww(d)(5)(B), which dictates that "[t]he Secretary *shall* provide [the IME payment] in an amount computed in the *same manner* as the adjustment for such costs under regulations (in effect as of January 1, 1983)," except as modified by Congress. The Supreme Court has also stated that when it appears from the legislative history that an agency's interpretation "is not one that Congress would have sanctioned," a court should not defer to the agency's interpretation. *Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783. Not only is the legislative history concerning the purpose of the IME payment contrary to the Secretary's interpretation, the history demonstrates that the Secretary is given no discretion in the calculation. *See* H.R. Rep. No. 98-25, at 140-141 (AR at 1029-30); *see also* H. R. Rep. No. 99-241, at 15 (1986), *reprinted in* 1986 U.S.C.C.A.N. 579, 593.

A court is required to defer to an agency's interpretation of its own regulation "only when the . . . regulation is ambiguous." *Christensen v. Harris County*, 529 U.S. 576, 588, 120 S. Ct. 1655, 1663 (2000). A court shall not defer to an agency's interpretation of its own regulation when an "alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 2386-87 (1994) (*citing Gardebring v. Jenkins*, 485 U.S. 415, 430, 108 S. Ct. 1306, 1314 (1988)). Even if a court accepts the agency's interpretation of its regulation, the court "must then consider whether the regulation so interpreted is consistent with the statute under which it is promulgated." *Cheshire Hosp. v. New Hampshire-Vermont Hospitalization Serv., Inc.*, 689 F.2d 1112, 1118 (1st Cir. 1982) (*citing United States v. Larinoff*, 431 U.S. 864, 873, 97 S. Ct. 2150, 2156 (1977)).

Although the Secretary is generally entitled to some deference in interpreting his own regulations when those regulations are ambiguous, the "weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *United States v. Mead*

Corp., 533 U.S. 218, 228, 121 S. Ct. 2164, 2172 (2000) (*citing Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161 (1944)).

The Secretary's factual findings must be supported by "substantial evidence." This standard "is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401, 91 S. Ct. 1420, 1427 (1971) (quoting *Consolidated Edison Co. of New York v. NLRB*, 305 U.S. 197, 229, 59 S. Ct. 206, 217 (1938)); *see also Stevenson v. Chater*, 105 F.3d 1151, 1153 (7th Cir. 1997).

IV. ARGUMENT

The Secretary's determination that research time may not be included in the IME FTE count is arbitrary and capricious, not in accordance with law, and must be reversed. The Secretary's interpretation of the IME statute is not entitled to deference because the statute unambiguously requires payment for any indirect costs of medical education and requires that the adjustment be calculated in the same manner as it was in 1983. 42 U.S.C. § 1395ww(d)(5)(B). In 1983, the calculation included research time. Furthermore, the IME regulation that was in effect in 1996 unambiguously requires the inclusion of research time in the IME FTE count, and the Secretary's interpretation to the contrary is not, therefore, entitled to deference. 42 C.F.R. § 412.105(f). The Secretary's attempt to rewrite the 1996 regulation to exclude research time is based upon a misreading of the agency's historical treatment of IME and constitutes an impermissible attempt to impose his 2001 regulation retroactively.

In addition, the Secretary's determination that the residents in question were not assigned to the PPS "portion" of the hospital is also contrary to law because the regulatory term "portion" unambiguously applies to geographic areas of the hospital that are subject to PPS. The Secretary's alternate conclusion that the residents were not assigned to geographic areas subject to PPS is *ulta vires* because the PRRB had no need to address this issue and therefore rendered no decision on the location of the residents. Finally, even if the Secretary had authority to decide this issue, his conclusion must be rejected as not based upon substantial evidence because he ignored conclusive evidence that the residents were, in fact, assigned to PPS portions of the hospital.

A. Research Time Must Be Included in the IME FTE Count

The Secretary's conclusion that research time may not be included in the IME FTE count is directly contrary to the plain language of the IME statute and the congressional policy behind that statute. The Secretary's regulation in FY 1996 contained no requirement to exclude research time from the IME FTE count, and the Secretary's claim of a "longstanding" policy of excluding research time is demonstrably false. The Secretary admitted prior to 2001 that research time is included in the IME FTE count, and his statements prior to 2001 in the *Federal Register* and the Medicare manuals reflect no longstanding policy to exclude research time.

1. *The Medicare Statute Requires the Secretary to Include Resident Research Time in the IME FTE Count*

The Medicare statute requires the Secretary to include research time in the IME FTE count. The statute uses the phrase "indirect costs of medical education" without limiting that term in any way to the subset of costs related to direct patient care. 42 U.S.C. § 1395ww(d)(5)(B). The statute also requires the Secretary to calculate the IME payment in the "same manner" as it was in 1983, except as altered by Congress. *Id.* In 1983, the IME FTE count included research time. Moreover, Congress designed the IME adjustment as a proxy measurement for the indirect costs of medical education. As a proxy measurement, the IME adjustment is intended to account for intangible operating costs associated with medical education, not just the operating costs associated with the use of residents in patient care. Finally, a later congressional enactment demonstrates that research time is included in the IME FTE count for those residents assigned to the hospital: Congress amended the IME statute to permit the inclusion of residents assigned to non-hospital settings and specifically required that these residents—and only these residents—be engaged in direct patient care.

a. The IME Statute Requires the Secretary to Include All Costs of the "Education Process" When Calculating a Provider's IME Payment Adjustment

The Secretary's direct patient care requirement violates the plain meaning of the statute creating the IME payment adjustment. The statute requires that the Secretary "shall provide for an additional payment amount for . . . hospitals [subject to PPS] with indirect costs of medical education . . . ." 42 U.S.C. § 1395ww(d)(5)(B). The law unambiguously requires the Secretary

to take into account all of a hospital's "indirect costs of medical education" when calculating its IME adjustment. The statute says nothing about limiting the adjustment to the subset of medical education costs that involve direct patient care. Rather than imposing a direct patient care requirement, the statute provides hospitals with an increased payment for the "indirect costs of medical education," regardless of whether those education costs are for patient care, research, or other activities related to medical education. *See Riverside Methodist Hosp. v. Thompson*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341 (S.D. Ohio 2003) (AR at 1035-43).

> Congress recognized that these costs result from:
>
> factors such as *severity of illness* of patients requiring the *specialized services and treatment programs* provided by teaching institutions and the *additional costs associated with the teaching of residents*.
>
> The latter costs are understood to include the additional tests and procedures ordered by residents as well as the extra demands placed on other staff as they participate in the *education process*. . . . [T]hese *indirect teaching expenses* are not to be subjected to the same standards of 'efficiency' implied under the DRG prospective system, but rather . . . they are legitimate expenses involved in the postgraduate medical education of physicians which the medicare program has historically recognized as worthy of support under the reimbursement system.
>
> The adjustment for indirect medical education costs is only a proxy to account for a number of factors which may legitimately increase costs in teaching institutions.

H.R. Rep. No. 98-25, at 140-41 (emphasis added) (AR at 1029-30). Congress was, therefore, concerned with a broad array of expenses related to teaching residents, and the IME adjustment was intended to compensate hospitals for these expenses. *Id.* Congress specified that indirect "teaching expenses" were legitimate, and these legitimate expenses include the demands on staff that participate in the "education process." *Id.*; *see also R.I. Hosp.*, 501 F. Supp. 2d at 286. Congress did not speak narrowly of costs related to direct patient care. Instead, Congress spoke of "teaching" and the "education process" more broadly, to encompass all expenses legitimately related to a resident's educational program, including research. H.R. Rep. No. 98-25, at 140-41.

As the *Riverside* court stated, "[T]here is nothing in the statute, or in the statutory formula for estimating [IME] costs, to indicate that Congress considered only the costs attributable to residents providing direct care and treatment of the hospital's patients (only one of the activities involved in a required residency program) as causing the indirect increase in the hospital's operating costs." [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶

301,341, at 805,021 (AR at 1040). To the contrary, as the court noted, "indirect medical education costs are virtually impossible to quantify in that they include not only costs directly caused by residents in actually caring for and treating patients, but also costs indirectly caused by the very nature of teaching hospitals." *Id.* at 805,022 (AR at 1041).

b. The IME FTE Count Must Be Calculated in the Same Manner as Under 1983 Regulations

Congress required that the Secretary compute the IME FTE count "in the same manner as" it was computed under the regulations that were in effect as of January 1, 1983. 42 U.S.C. § 1395ww(d)(5)(B). The Secretary's direct patient care requirement violates this statutory mandate because it excludes resident time that was included in the FTE count under the rules in effect on January 1, 1983. The cost reporting form instructions for counting residents that were in place on January 1, 1983 were simple and unambiguous:

> Enter the number of interns and residents (full-time equivalent) in an approved program for the hospital only. The number of FTE interns and residents is the sum of:
>
> 1. Interns and residents employed 35 hours or more per week, and
>
> 2. One half of the total number of interns and residents working less than 35 hours per week regardless of the number of hours worked. Interns and residents in unapproved programs and those on the hospital's payroll who only furnish services at another site must not be included in the count. (See HCFA-Pub. 15-1, §2802G.)

PRM § 1208.2 (AR at 995).[6] There were only two questions that a hospital needed to answer to determine whether to count a resident on the cost report: 1) was the resident in an approved program? and 2) was the resident at the hospital? Affirmative answers to these questions meant that the resident's time was included. The instructions that were in effect in 1983 did not direct hospitals to exclude resident time spent in research, grand rounds, supervising other residents or medical students, or any other activity.

In fact, program requirements established by the Accreditation Council for Graduate Medical Education ("ACGME") in 1983 specifically required a resident research component in approved programs. *'82-'83 Directory of Residency Training Programs*, at 18 (AR at 1046). The accreditation rules required that research be "in addition to" clinical instruction. *Id*. Thus,

[6] The cost reporting instructions were virtually identical to the regulations that were in effect at the time. *See* 47 Fed. Reg. 43,310 (Sept. 30, 1982) (AR at 991).

when Congress enacted the IME payment provision, "medical education" at a hospital necessarily included research and other educational activities that were required components of an approved graduate medical residency program. The accreditation rules and the cost reporting instructions from 1983 demonstrate that the FTE count in 1983 included time spent by residents in research as part of their approved programs. The Secretary's exclusion of resident research time violates the statute's plain mandate that the Secretary calculate the FTE count "in the same manner" as it was calculated in 1983.

c. The IME Resident Count Is a Proxy for Measuring Indirect Teaching Costs

The IME adjustment compensates teaching hospitals for higher-than-average operating costs that statistically correlate with the presence and intensity of residents training in an institution. *Report to the Congress, Rethinking Medicare's Payment Policies for Graduate Medical Education and Teaching Hospitals*, Medicare Payment Advisory Commission, Aug. 1999 ("MEDPAC Report"), at 5 (AR at 945). Regardless of the nature of the costs, they are measured by a congressional formula that is a "proxy," or substitute, for any attempt to itemize and quantify such costs—a formula that makes no distinction as to the nature of the costs incurred. *Univ. Med. Ctr.*, 2007 WL 891195 at *3. The IME adjustment is calculated on the basis of a hospital's teaching intensity, which is measured by the ratio of the hospital's full-time equivalent interns and residents to beds. H.R. Rep. No. 98-25, at 140 (AR at 1029); *see also* 42 U.S.C. § 1395ww(d)(5)(B). Congress used this formula as "a proxy to account for a number of factors which may legitimately increase [operating] costs in teaching institutions." H.R. Rep. No. 98-25, at 140-41 (AR at 1029-30).

This proxy was necessary because, as the court observed in *Riverside*, it is not possible to identify or measure all the higher operating costs incurred by teaching hospitals, due to their very nature as teaching institutions:

> It is precisely because the indirect costs cannot be adequately itemized and quantified that Congress devised a formula based on the degree of teaching intensity in a particular hospital, as a substitution for any other method of reimbursing such costs. If Congress had believed that the indirect medical education costs of a teaching hospital could be separately identified and quantified, and that higher direct patient care costs could be so determined from the hospital's records, then Congress could easily have qualified its formula for

> reimbursement to restrict the number of FTE residents to a number based only on hours that residents spent providing "patient care." It obviously did not do so.

Riverside, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341, at 805,023 (AR at 1042).

Congress's primary concern—which the Secretary "explicitly acknowledged" when PPS was enacted—was that the standard PPS payment rates are inadequate to compensate teaching hospitals fairly for "the specialized services and treatment programs" and "the additional costs associated with the teaching of residents." H.R. Rep. No. 98-25, at 140 (AR at 1029); *see also* S. Rep. No. 98-23, at 52 (AR at 1032). The IME payments were intended to offset the operating costs associated with providing more specialized services and the "education process"—not just the operating costs associated with the use of residents in patient care. H.R. Rep. No. 98-25, at 140 (AR at 1029). "In short, there is nothing in the purpose of the IME statute, or its statutory formula, that shows any intention of Congress to base reimbursement on a method that excludes all required residency program activities from consideration except those considered by the Secretary to involve a resident providing direct patient care to a specific patient." *Riverside*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341, at 805,022 (AR at 1041).

d. Congress's Requirement of Direct Patient Care in Non-Hospital Settings Confirms That Direct Patient Care Is Not Required in Hospital PPS and Outpatient Settings

In 1996, the statute contained no direct patient care requirement for IME FTEs. The statute was amended in 1997 to expand the IME FTE count by providing, for the first time, that a resident working in a *non-hospital* setting may be included in a hospital's IME FTE count, but only if the resident is engaged in "patient care activities." *See* 42 U.S.C. 1395ww(d)(5)(B)(iv). If Congress had intended to impose a direct patient care requirement on all resident time, it easily could have amended the statute to do so. Congress instead required only that residents in non-hospital settings be engaged in direct patient care, demonstrating that Congress did not intend this requirement for other residents. The imposition of a patient care requirement specifically for counting residents in non-provider settings implies the exclusion of the same requirement when counting residents in the hospital. This follows from a canon of interpretation —*unius est exclusio alterius*—holding that to express or include one thing implies the exclusion of the other,

or of the alternative. *TRW Inc. v. Andrews*, 534 U.S. 19, 28, 122 S. Ct. 441, 447 (2001); *Nat'l R. R. Passenger Corp. v. Nat' Ass'n of R. R. Passengers*, 414 U.S. 453, 458, 94 S. Ct. 690, 693 (1974). This is especially true when the relevant provisions are so close together.

2. *The IME Regulation Unambiguously Requires the Secretary to Include Resident Research Time in Plaintiff's IME FTE Count*

The Secretary's new requirement that only a resident's time involving direct patient care may be counted in calculating a hospital's IME adjustment is contrary to the Medicare IME regulation in effect during Plaintiff's 1996 cost year. *R.I. Hosp.*, 501 F. Supp. 2d at 289; *Univ. Med. Ctr.*, 2007 WL 891195 at *9. The regulation in effect then unambiguously allows the Provider to include research time in its IME FTE count. *Univ. Med. Ctr.*, 2007 WL 891195, at *9. During fiscal year 1996, the regulation that governed the count of IME FTEs contained only two requirements: the resident had to be "enrolled in an approved teaching program," and the resident had to be assigned either to the "portion of the hospital subject to the prospective payment system" or to an "outpatient department of the hospital." 42 C.F.R. § 412.105(g). The regulation clearly did not include a direct patient care requirement. *R.I. Hosp.*, 501 F. Supp. 2d at 289 ("There is nothing in subparagraphs (i) or (ii) that requires a resident to provide direct patient care in order to be counted"); *Riverside*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341, at 805,019 (AR at 1038) ("this regulation does not contain, or even implicitly allude to, any requirement that only resident hours spent in providing actual patient care can be included for purposes of the IME FTE resident count"). Thus, as the *Rhode Island* court held, the Secretary has "engrafted an additional requirement that is not contained in the Regulation as written." 501 F. Supp. 2d at 289.

In fact, the regulation contemplates that time spent in educational activities not involving direct patient care will be included. The regulation states that FTE status "is based on the total time necessary to fill a residency slot," as compared to the total time spent providing patient care. *R.I. Hosp.*, 501 F. Supp. 2d at 289. Because approved residency programs generally require residents to spend time in research rotations to learn how to conduct and interpret medical research, the regulation contemplates that time spent in research training as part of a resident's approved program will be included. *See Riverside*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341, at 805,019 n.6 (AR at 1038-39).

3. *The Secretary Had No Longstanding Policy Excluding Research Time*

The Secretary attempts to avoid the clear mandate of the regulation by claiming that the agency has historically excluded research time from the IME FTE count. (AR at 10-11); *see also* 66 Fed. Reg. 39,828, 39,896-99 (Aug. 1, 2001) (claiming that the 2001 amendment to the IME regulation excluding research time from the IME FTE count was merely a "clarification" of the agency's "longstanding policy regarding time that residents spend in research"). The Secretary in fact had no such longstanding policy. Guidance provided by CMS officials, CMS manuals, and CMS's *Federal Register* notices all demonstrate that the Secretary either had no policy with respect to counting resident time spent in research activities or that the Secretary actually encouraged hospitals to count resident research time.

a. The Secretary Has Admitted That the IME Regulations Prior to 2001 Contained No Direct Patient Care Requirement

Through CMS, the Secretary has stated directly that resident research time could be included in a hospital's IME FTE count. *See* Letter from Tzvi Hefter, Dir., HHS, to Thomas Curtis, President, Nat'l Compliance Group (Sept. 24, 1999) (AR at 1059); Letter from Tzvi Hefter, Dir., HHS, to unknown recipient (Sept. 24, 1999) (AR at 1061). CMS stated that it "interprets the phrase 'patient care activities' broadly to include any patient care oriented activities that are part of the residency program," including "patient care related research as part of the residency program." Letter from Hefter to unknown recipient (Sept. 24, 1999) (AR at 1061). Research could be included in the IME payment calculation "as long as the residents are primarily involved in patient care oriented activities and other program requirements are met." *Id.* Research is "an allowable activity and may be counted for IME purposes." Letter from Hefter to Curtis (Sept. 24, 1999) (AR at 1059). The Secretary's statements in 1999 clearly contradict his later assertions that he has a "longstanding policy" of not counting resident research time in the IME FTE calculation.

b. The Secretary's *Federal Register* Notices Do Not Demonstrate a "Long-Standing Policy" Supporting the Imposition of a Direct Patient Care Requirement on the IME Resident Count

The Secretary is unable to cite any rule or policy statement prior to 2001, when the research exclusion was first proposed, that clearly demonstrates a policy of excluding time not

involving the care of a particular patient from the IME resident count. Consequently, he is forced to construct an argument based on inferences from earlier statements that IME is intended to reimburse hospitals only for higher patient care costs. Among the citations relied upon by the Secretary are statements contained in the *Federal Register* in 1983 and 1985 (48 Fed. Reg. 39,844 (Sept. 1, 1983) and 50 Fed. Reg. 35,646, 35,681-82 (Sept. 3, 1985)) (AR at 7-8). Neither of these entries, however, refers to a direct patient care requirement for the IME count.

Moreover, the cited 1985 *Federal Register* statements actually undermine the Secretary's position. First, the Secretary acknowledged that the IME payment was created because graduate medical education programs "by their very existence within institutions, increased the hospitals' costs in many ways. These indirect costs may include increased department overhead . . . ." 50 Fed. Reg. at 35,681 (emphasis added). Second, the Secretary's response to a question on the treatment of resident time spent "on-call" demonstrates that the Secretary was not applying a direct patient care requirement to the IME resident count in 1985. In that year, the method for determining IME FTEs was changed from calculating the actual hours worked to counting the number of residents assigned to the hospital on September 1. *Id*. at 35,678. The Secretary stated, "The new method of counting interns and residents based on their assignment to a hospital on September 1 eliminates the need to consider on-call time." *Id.* at 35,680. Thus, the Secretary had been including on-call hours when calculating the FTE count. If the Secretary had been applying a policy to exclude time spent by residents not involving the care of a particular patient from the IME resident count, he would have excluded time spent by residents "on-call." When a resident is on-call, he or she is, by definition, not treating a patient; rather, the resident is available to provide patient care should the need arise.

c. The Secretary's Medicare Manuals Did Not Require Research to Be Excluded From the IME FTE Count

Prior to 2001, neither the Medicare Intermediary Manual ("MIM"), nor the PRM, required that research time be excluded from the count of IME FTEs. For example, in the MIM, CMS explains the process for auditing IME resident counts:

> Test that the following [interns and residents] are not included in the indirect medical education count:
> - in unapproved programs;
> - working at another provider;
> - assigned to excluded units;

- replacing non-physician anesthetists; or
- assigned to freestanding clinics such as family practice centers or nonprovider clinics.

Medicare Intermediary Manual ("MIM"), Pub 13, Part 4, Ch. 2 § 4198 (AR at 1062). The audit procedure does not include any reference to excluding research time that is part of an approved medical education program.

The Secretary also asserts that the policy was previously articulated in PRM § 2405.3.F. (AR at 9-10); *see also* 66 Fed. Reg. 22,646, 22,699-700 (May 4, 2001). PRM § 2405.3.F cannot reasonably be interpreted as the Secretary suggests. The provision first instructs intermediaries to count residents who are in approved programs and to exclude residents who are not in approved programs. It then acknowledges that there are situations where the circumstances are unclear as to whether a resident is in an approved program. PRM § 2405.3.F.2 (AR at 1066-76). The manual instructs intermediaries not to consider an *individual* as being in an approved program—and hence to exclude that individual from the resident count—if "the individual is engaged exclusively in research." *Id.*

The clear focus of this manual provision is to identify residents who are not in approved programs and who should not be counted *at all* in the resident count. The manual provision does not instruct intermediaries to carve up the time of residents who are in approved programs based on whether they are performing hands-on patient care. Indeed, compliance with such a requirement would require detailed time records—down to the fraction of an hour—recording for each resident whether he or she was providing hands-on patient care at any particular moment. Nowhere in Medicare regulations or guidelines are such records required or even suggested.

d. The Secretary Misrepresents the Reasonable Cost Rules

The Secretary argues that the IME payment is subject to reasonable cost principles because the IME adjustment is an add-on to the inpatient PPS per-case payment, which is based upon hospitals' reasonable operating costs for providing patient care. (AR at 7.) The Secretary further argues that because research costs are unallowable under 42 C.F.R. § 413.85 (designated as 42 C.F.R. § 413.90 in 1996), research time should be excluded from the IME FTE count. (AR at 5.) The Secretary has mischaracterized the IME payment, which is a proxy for indirect medical education costs that is not subject to the reasonable cost rules. *See* argument at §

IV.A.1, *supra*. Moreover, even if the reasonable cost rules apply, research would not be excluded from allowable costs as the Secretary asserts.

Most fundamentally, by imposing a direct patient care requirement on the IME FTE count, the Secretary is mixing apples with oranges; he is attempting to apply a cost-finding technique—identification of particular expenses associated with patient care—to a payment formula that Congress adopted as a *substitute* for cost-finding, precisely because it determined that the indirect costs of medical education cannot be itemized and quantified. The IME formula is not dependent upon the allowability of any particular types of costs. Instead, the formula relies on teaching intensity (as measured by the hospital's resident-to-bed ratio) as a substitute for determining allowable costs. Thus, the Secretary's methodology is wholly inconsistent with the IME statute, and the Secretary's effort to equate time spent by residents in educational research to unallowable research costs is unavailing.

Furthermore, the Secretary presumes, erroneously, that the research rotations at issue would otherwise constitute unallowable research costs under 42 C.F.R. § 413.90. In addition to being wholly inconsistent with the IME statute, the Secretary's argument fails because the residency rotations at issue are allowable costs under 42 C.F.R. § 413.90. The Medicare regulation governing research costs excludes costs incurred for research purposes over and above "usual patient care" and "*related activities*." (emphasis added). In applying this principle, the regulation states: "If research is conducted in conjunction with, and as a part of, the care of patients, the costs of usual patient care are allowable . . . ." 42 C.F.R. § 413.90(b)(2) (1996). It further states that "related activities to serve the provider's administrative and program needs, are not excluded as allowable costs . . . ." *Id.*

Indeed, the Secretary specifically acknowledges that research that involves *usual patient care* activities is counted for IME FTEs. (AR at 6.) The Secretary then equates the phrase "usual patient care," to mean time spent in the diagnosis and treatment of a particular patient. (AR at 6, 9.) The Secretary's interpretation of "usual patient care" is incorrect and unsupported by either the regulations or the case law regarding the allowability of residency program costs. The phrase "usual patient care" for hospital services means "costs related to patient care," as defined in 42 C.F.R. § 413.9. That regulation defines reasonable costs to include all necessary and proper costs incurred in furnishing the services. The phrase "necessary and proper costs" is

defined to include all costs "that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities." 42 C.F.R. § 413.9(b)(2).

Moreover, the Medicare statute defines "inpatient hospital services" to include the services of an intern or a resident-in-training in an approved training program. 42 U.S.C. § 1395x(b). Similarly, the cost of services of interns and residents provided to an inpatient of a hospital with an approved teaching program are includable in allowable costs under Medicare Part A. PRM § 2120.A. Finally, the Medicare statute defines professional services rendered for the *general benefit* of patients in a hospital as being a reasonable cost of the hospital. 42 U.S.C. § 1395xx(a)(1)-(2). All of these definitions demonstrate that the costs of residents and interns engaged in research as part of an approved training program are included in a hospital's "costs of usual patient care . . . and related activities," provided the research is conducted to serve "the provider's administrative and program needs." 42 C.F.R. § 413.90(b)(2). In other words, when the research is part of the hospital's approved teaching program, it is an allowable cost under 42 C.F.R. § 413.90.

The federal courts have rejected the Secretary's interpretation of research costs. One court has stated that the costs of residents engaged in research as part of their approved residency programs are allowable if the research is intended solely to develop the residents' practical skills and techniques applicable to patient-care activities. The court held that "the Secretary's determination that the research rotations are for over and above usual patient care, is not supported by substantial evidence." *Univ. of Iowa Hosps. and Clinics v. Shalala*, No. 3-96-CV-10012, slip op. at 30 (S.D. Iowa Feb. 12, 1997) (AR at 1101).

The Sixth Circuit interpreted the concept of usual patient care to require "only that the educational programs contribute to the quality of care of the Hospital's Medicare patients." *Univ. of Cincinnati v. Bowen*, 875 F.2d 1207, 1211 (6th Cir. 1989). The court found that "accredited programs required as a part of the residents' training . . . *ipso facto* contribute to the quality of care received by the Hospital's Medicare patients." *Id.* In fact, the court held that many resident tasks that did not include direct patient care were allowable costs under the medical education regulations because they inevitably contributed to the overall quality of patient care in the hospital. *Id.* at 1210-1211. The court explained that the medical education regulation "only requires educational 'activities' that ultimately enhance the quality of Medicare patient care, not direct 'services' to those patients. The regulations are therefore satisfied as long

as the residents return to the provider for their clinical training to enhance services to its Medicare patients." *Id.* at 1211. Thus, the question was not whether a resident was providing direct patient care, but rather whether the activity of the resident contributed to his or her ability to provide care to the hospital's Medicare patients.

Accordingly, even if the IME regulation were construed as subject to reasonable cost reimbursement principles, these principles would dictate that resident time spent in research rotations be included in Plaintiff's IME FTE count. These rotations are designed to develop the residents' practical skills and techniques and are conducted in conjunction with and as a part of usual patient care and related activities. As such, contrary to the Secretary's assertion, research rotations were considered in the analysis of increased teaching hospital operating costs that led to the IME adjustment. Thus, even by the Secretary's reasoning, these research rotations must be included in the IME count because the IME adjustment was intended to compensate for the higher allowable costs of teaching hospitals, such as the educational research training activities at issue in this appeal.

4. *The Secretary May Not Retroactively Impose His 2001 Rule*

As explained above, Plaintiff contends that the Secretary's exclusion of research from the IME FTE count is contrary to the Medicare statute and therefore invalid. Assuming, *arguendo*, that the Secretary may exclude research from the IME FTE count, he may not do so retroactively. The Secretary's new IME research exclusion is not an interpretation of a "longstanding policy." *R.I. Hosp.*, 501 F. Supp. 2d at 289; *Univ. Med. Ctr.*, 2007 WL 891195, at *9-10; *Riverside*, [2003-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 301,341 (AR at 1043). Instead, it is a new substantive rule, which could only be effective on October 1, 2001, after it was promulgated pursuant to notice and comment rulemaking. Therefore, the Secretary's attempt to apply his 2001 amendment to Plaintiff for activities that occurred prior to the regulation's effective date of October 1, 2001 constitutes retroactive rulemaking in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*

The Secretary may not penalize Plaintiff for violating previously unpublished rules. 5 U.S.C. § 552(a)(1). The APA mandates that rules may only take effect in the future. 5 U.S.C. § 551(4). The APA defines a "rule" as "the whole or a part of an agency statement of general or particular applicability and *future effect* . . . ." *Id.* (emphasis added); *see also Bowen v.*

Georgetown Univ. Hosp., 488 U.S. 204, 216, 109 S. Ct. 466, 476 (1988) (Scalia, J., concurring). For a rule to have the force and effect of law, it must be a substantive rule and have been properly promulgated, usually by following the procedural requirements of the APA. *Chrysler Corp. v. Brown*, 441 U.S. 281, 301-02, 99 S. Ct. 1705, 1717-18 (1979). Substantive rules must generally be promulgated through notice and comment rulemaking. 5 U.S.C. § 553.

The Supreme Court has held that an agency, such as CMS, may not enact retroactive rules unless Congress has explicitly authorized the agency to do so. *Georgetown Univ. Hosp.*, 488 U.S. at 208, 109 S. Ct. at 471-72. The Court stated:

> [C]ongressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms.

Id. (citations omitted); *see also Univ. of Iowa v. Shalala*, 180 F.3d 943, 951 (8th Cir. 1999) ("[w]hen Congress delegates legislative authority to an administrative agency, courts will presume that the delegation forbids the agency from creating retroactive prescriptions, and only express congressional authority will overcome this presumption.").

The Secretary may not apply his 2001 regulation retroactively because, in 2001, Congress had not expressly authorized the Secretary to enact retroactive rules. *Georgetown Univ. Hosp.*, 488 U.S. at 215, 109 S. Ct. at 475. The statute creating the IME adjustment, 42 U.S.C. § 1395ww(d)(5)(B), contains no express grant of authority to enact retroactive regulations. The Supreme Court has held that the Medicare statute does not grant the Secretary of Health and Human Services the power to enact retroactive rules. *Georgetown Univ. Hosp.*, 488 U.S. at 215, 109 S. Ct. at 475. Because the Secretary had no grant of authority from Congress in 2001 to enact retroactive rules, the Secretary may not impose his patient-care requirement for resident research that occurs prior to the rule's effective date of October 1, 2001. *R.I. Hosp.*, 501 F. Supp. 2d at 288. Accordingly, the patient care requirement in the 2001 rule may not be applied to Plaintiff's 1996 cost reporting period.

B. The Residents Were Assigned to PPS Portions of the Hospital

As an alternate justification for excluding the FTEs in question, the Secretary has redefined the requirement that residents be assigned to a "portion" of the hospital subject to PPS.

(AR at 11-13.) Both the *Rhode Island Hospital* and *University Medical Center* courts properly rejected this interpretation as contrary to the plain meaning of the regulation, which refers to geographic "portions" of the hospital. *R.I. Hosp.*, 501 F. Supp. 2d at 290; *Univ. Med. Ctr.*, 2007 WL 891195, at *9-10. Thus, the Secretary's interpretation is not entitled to deference. The Secretary also concludes that Plaintiff did not demonstrate that the residents were assigned to geographic portions of the hospital subject to PPS. This latter conclusion is *ultra vires* because the Secretary may only reverse a "decision" of the PRRB, and the PRRB made no "decision" on this point because it was stipulated by the parties beforehand. Moreover, the Secretary's conclusion must be rejected as not supported by substantial evidence because he ignores the findings of his auditors, who after reviewing Plaintiff's claims for several years, determined, correctly, that the residents were indeed assigned to PPS portions of the hospital.

1. *"Portion" of the Hospital Subject to PPS Refers to a Physical Location*

Apparently recognizing that his 2001 regulation is a new rule that may not be imposed retroactively, the Secretary attempts to reinterpret the regulation in effect for FY 1996 to find an alternative basis for disallowing the FTEs in question. According to the Secretary, the requirement that a resident be "assigned to the *portion* of the hospital subject to the prospective payment system," does not mean, as its plain language suggests, that a resident must be assigned to a physical area within the hospital that is subject to PPS. (AR at 11-12 (interpreting 42 C.F.R. § 412.105(f)(5)) (emphasis added).) Instead, according to the Secretary, the regulatory term "portion" of the hospital subject to PPS means that the resident must be assigned to a "'sphere or scope of operation or action'" of the hospital subject to PPS. (AR at 12.) In other words, according to the Secretary, "portion of the hospital" refers to a functional assignment rather than to a geographical assignment. The Secretary ignores his own prior statements and precedents rejecting his tortured analysis of the regulation. *R.I. Hosp.*, 501 F. Supp. 2d at 289-90; *Univ. Med. Ctr.*, 2007 WL 891195, at *8-10.

The issue in the *Rhode Island Hospital* and *University Medical Center* cases is precisely the same as the issue presented here: whether time spent in research training required under Medicare-approved medical residency programs should be included in a hospital's FTE count for purposes of determining IME payment. The court in *Rhode Island Hospital* specifically held that "reading into the requirement that a resident must be 'assigned' to 'the portion of the hospital

subject to the prospective payment system' a further requirement that, while so assigned, the resident must perform direct patient care is inconsistent with both the plain language of the Regulation and its stated purpose." 501 F. Supp. 2d at 290. In *University Medical Center*, the court also held that the Secretary's position was impermissible. 2007 WL 891195, at *8-9.

As explained above, the Secretary's Medicare Intermediary Manual directs auditors to exclude from the FTE count residents who are " in unapproved programs; working at another provider; assigned to excluded units; replacing non-physician anesthetists; or assigned to freestanding clinics such as family practice centers or nonprovider clinics." MIM § 4198, Ex. A-10 (AR at 1062-64). None of these tests requires an auditor to determine whether a resident is assigned to a "sphere or scope of operation or action" of the hospital subject to PPS. To the contrary, the regulatory requirement that residents be assigned to a "portion" of the hospital subject to PPS is implemented in the instruction to omit residents "assigned to excluded units." This demonstrates that the Secretary has historically interpreted the term "portion" as referring to geographical areas of the hospital. The auditor determines the "unit" of the hospital to which the resident is assigned, and if the resident is assigned to a geographical unit excluded from PPS, then that resident is also excluded from the IME FTE count.

The Secretary's instructions in the MIM are consistent with his longstanding interpretation of the IME regulation. When the regulation was promulgated in 1983, he explained that residents assigned to excluded units, such as psychiatric and rehabilitation units, could not be included in the IME FTE count because those units were paid under the reasonable cost system, which "already include[d] the indirect cost of medical education." 48 Fed. Reg. 39,752, 39,778 (Sept. 1, 1983); *see also R.I. Hosp.*, 501 F. Supp. 2d at 290. Thus, in 1983, the Secretary interpreted "portion" to refer to geographical units of the hospital, and a resident was included in the IME FTE count unless he or she was assigned to an excluded unit. In 1985, the Secretary stated this even more explicitly: "time spent in . . . excluded units is not counted for purposes of the indirect medical education payment since these settings are not subject to the prospective payment system." 50 Fed. Reg. at 35,678. The Secretary's current assertion that he has always interpreted the regulatory term "portion of the hospital subject to [PPS]" to refer to functional activities, rather than geographical units, is simply not credible.

2. *The Residents Were in Fact Assigned to PPS Portions of the Hospital*

After having his legal arguments repeatedly rebuffed by the courts, the Secretary grasps at one final straw: he maintains that Plaintiff's residents were not assigned to physical areas of the hospital subject to PPS. (AR at 12.) The Secretary's conclusion must be rejected. This portion of the Administrator's decision is *ultra vires* because this issue was not before the PRRB. Moreover, even if the Administrator had the authority to make a determination about the location of these residents, the Administrator's decision is not based upon substantial evidence and must be rejected because the Administrator ignores the findings of his own auditors and points to no evidence that the residents were in non-PPS portions of the hospital.

a. The Secretary's Determination Is *Ultra Vires*

The Secretary's determination as to the location of Plaintiff's residents is *ultra vires* because his decision impermissibly goes beyond the scope of the PRRB decision. The Medicare statute empowers the Secretary to "reverse[], affirm[], or modif[y]" a PRRB "decision." The PRRB made no decision about the location of the residents. The PRRB's decision is clear that "[t]he single issue in this case is whether the time spent by residents conducting research as a part of an approved residency program should be included [in] the IME calculation." (AR at 135.) The PRRB limited its review to this legal issue because the parties stipulated in advance that no factual issues remained in dispute, and the sole issue remaining in dispute was whether research time could be included in the IME FTE count. (AR at 131-36, 149-50.) In limiting its review to the pure legal issue, the Board stated, "It is undisputed that the residents at issue in this case were enrolled in an approved GME program and that they worked in either the portion of the Provider's facility subject to PPS or an outpatient area." (AR at 131-36) (emphasis added). Because these facts were not disputed, the Board did not hold an evidentiary hearing, and the appeal was submitted to the Board based upon the parties' briefs. (AR at 135, 147-50.)

If the Secretary believed that the record did not establish that the residents were assigned to PPS portions of the hospital, the appropriate course was for the Secretary to remand the case to the PRRB for further proceedings. In promulgating the remand regulation, the Secretary explained that "[t]he essential purpose of the remand authority is to have the Board consider additional evidence or issues essential to a full development of the record." 48 Fed. Reg. at 45,770. The Secretary chose not to exercise his remand authority within the 60-day deadline for

him to act on the PRRB's decision. 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1875(g)(2). Instead, he chose to reverse the Board's decision, primarily focusing on the legal issue that is now before this Court. Having done so, the Secretary was constrained by the scope of the Board's decision, and he could not permissibly delve into matters that were not before the Board.

b. The Secretary's Decision Is Not Based on Substantial Evidence

Moreover, the Secretary's determination regarding the location of the residents is not based on substantial evidence, which requires that the Secretary base his findings on "more than a mere scintilla" of evidence. *Richardson v. Perales*, 402 U.S. 389, 401, 91 S. Ct. 1420, 1427 (1971); *Stevenson v. Chater*, 105 F.3d 1151, 1153 (7th Cir. 1997). Instead, his conclusions must be based upon "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Perales*, 402 U.S. at 401, 91 S. Ct. at 1427; *Stevenson*, 105 F.3d at 1153. The Secretary points to no evidence that the residents were assigned to non-PPS portions of the hospital, and he ignores extensive evidence in the record to the contrary.

The Secretary cites no evidence that any residents were actually assigned to excluded units of the Provider. Instead, the Secretary claims that Plaintiff did not adequately show that the residents were in PPS portions of the hospital. The Secretary focuses on the term "hospital complex," which Plaintiff's personnel used on questionnaires sent to the various departments that train residents in order to gather information regarding the FTEs. (AR at 12-13.) The Secretary argues that the "hospital complex" is not the same as the PPS portion of the hospital. *Id.*

The Secretary ignores the nearly *four-year* review of these residents conducted by auditors from his own contractor, the Medicare fiscal intermediary. Discussions between Plaintiff and the Medicare auditors began at least as far back as May 2003. (AR at 2191.) Plaintiff submitted documentation throughout 2005. *See, e.g.*, (AR at 2162, 2102-17). At the time final position papers were filed with the PRRB in March 2006, a number of issues in addition to IME research were still in dispute. (AR at 160-67, 199-232, 1548-55, 1586-93.) During this entire period, Medicare auditors reviewed each resident in detail. As a result of this review, the issues under appeal eventually narrowed, and the parties settled all issues other than IME research. (AR at 147-50.) The IME research issue was itself narrowed to the purely legal issue of whether research time is includable in the IME FTE count. Thus, the parties stipulated before the Board in February 2007 that no factual issues remained in dispute. (AR at 149.)

As Plaintiff demonstrated to the satisfaction of the Secretary's auditors, only two areas within the hospital complex were excluded from PPS: Ward 4, the inpatient psychiatric ward, and the General Clinical Research Center ("GCRC"), a non-reimbursable cost center. (AR at 149, 199.) Plaintiff further demonstrated—and the Medicare auditors agreed—that no residents who trained in either Ward 4 or the GCRC were included in the IME FTE count. (AR at 149, 199, 288-95, 1433-95.) The residents at issue here were training in anesthesiology, internal medicine, neurology, orthopedic surgery, otolaryngology, pediatrics, plastic surgery, radiation oncology, radiology, and surgery. None were psychiatry residents who trained in Ward 4. (AR at 149, 199, 288-95, 1433-95.) Moreover, none of the resident time claimed by Plaintiff occurred in the GCRC. Based on its thorough review of the facts relating to the residents at issue, the Medicare fiscal intermediary explicitly stipulated that "[n]o factual disputes are at issue in this appeal," and the "sole issue" in the appeal was whether research is includable in the IME FTE count. (AR at 149.)

The Secretary tries to confuse this issue by pointing out that some of the forms completed by the departments contain greater specificity about the location of the residents within the hospital complex (*e.g.*, "Laboratory"), as though furnishing additional detail somehow casts doubt on Plaintiff's contention that these residents were in PPS portions of the hospital. To the contrary, all of the areas identified by the Secretary are in PPS portions of the hospital, as stipulated by the Secretary's auditors. None is an excluded unit. As the *Rhode Island* court correctly stated, the "regulations begin with the presumption that an area is covered by PPS, unless specifically exempted." 501 F. Supp. 2d at 290 (quoting *Alhambra Hosp. v. Thompson*, 259 F.3d 1071, 1074 (9th Cir. 2001)) (internal quotations omitted). Thus, each of the laboratories identified by the Secretary is in the PPS portion of the hospital.

The Secretary's auditors, after reviewing these claims for nearly four years, agreed that all the residents at issue here were assigned to portions of the hospital subject to PPS. This case was originally scheduled for a live evidentiary hearing before the PRRB on April 12, 2007, in which both parties would present testimony on any factual issues in dispute. Prior to the hearing, however, the parties resolved all factual disputes and entered into a stipulation, specifically stating both that the "sole issue" remaining in the appeal was whether research is includable in the IME FTE count and that "[n]o factual disputes are at issue in this appeal." (AR at 149-50.) The Secretary's conclusion that Plaintiff somehow failed to demonstrate that the residents were

assigned to PPS portions of the hospital flies in the face of the factual findings of his own auditors.[7]

The Secretary's attempt to cast doubt on the location of these residents is merely his last, desperate attempt to salvage his unlawful policy and deny Plaintiff the reimbursement to which it is entitled. The Secretary has not shown that any residents were assigned to units excluded from PPS, and the Secretary's auditors, after a nearly four-year review, determined that the residents were in PPS portions of the hospital, which was memorialized in a stipulation before the PRRB. The Secretary's conclusion is not supported by substantial evidence and must be rejected.

V. CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court grant its motion for summary judgment.

Respectfully Submitted,

University of Chicago Medical Center

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[7] The Secretary's statements about the parties' position papers before the Board merely prove Plaintiff's point that the Secretary's auditors painstakingly reviewed the location of these residents and concluded that they were in PPS portions of the hospital. (AR at 11 n.21.) The Secretary contends that because both Plaintiff and the Intermediary presented arguments in their final position papers on the location of the residents, the issue was somehow unresolved. *Id.* What the Secretary ignores, however, is that the final position papers were filed with the Board a full year before the hearing date. (AR at 2158-59, 2151-53.) The auditors continued their review during that time, and by the time of the hearing, the auditors were satisfied that this issue had been resolved and that the residents were, indeed, assigned to PPS portions of the hospital. (AR at 149.)

CERTIFICATE OF SERVICE

I hereby certify that I have electronically filed the foregoing Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment with the Clerk of Court using the Case Management/Electronic Filing System ("CM/ECF") system, which sent notification of such filing to the following:

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Dated: July 18, 2008.

APPENDIX TO THE MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

PART 1 OF 2

Westlaw.
Slip Copy
Slip Copy, 2007 WL 891195 (D.Ariz.), Med & Med GD (CCH) P 302,057
(Cite as: 2007 WL 891195 (D.Ariz.))

CUniversity Medical Center Corp. v. Leavitt
D.Ariz.,2007.

United States District Court,D. Arizona.
UNIVERSITY MEDICAL CENTER CORP.,
Plaintiff,
v.
Michael O. LEAVITT, Defendant.
No. 05-CV-495 TUCJMR.

March 21, 2007.

Diane M. Lindquist, Lewis & Roca LLP, Tucson, AZ, Gregory N. Etzel, Baker & Hostetler LLP, Houston, TX, for Plaintiff.
Peter Robbins, U.S. Dept of Justice, Washington, DC, for Defendant.

ORDER

JOHN M. ROLL, Chief United States District Judge.
***1** Pending before the Court are the parties' cross-motions for summary judgment. On February 15, 2007, Magistrate Judge Bernardo P. Velasco issued a Report and Recommendation (R & R) to the Court (Doc. No. 38), recommending that the Court deny Defendant's Motion for Summary Judgment (Doc. No. 19) and grant Plaintiff's Motion for Summary Judgment (Doc. No. 23). Defendant filed Objections to the R & R (Doc. No. 39). Plaintiff has not filed any Objections. For the reasons stated below, the Court adopts the Magistrate Judge's Report and Recommendation in its entirety.

I. BACKGROUND

The underlying facts and regulatory scheme [FN1] are set forth in greater detail in the R & R (at 5-7). Plaintiff, a teaching hospital, sought Medicare reimbursement for Indirect Medical Education (IME) for the time residents spent conducting research. Pursuant to statute, the Secretary of the United States Department of Health and Human Services contracted with a fiscal intermediary to audit the costs submitted by Medicare providers such as Plaintiff. In its audit of Plaintiff's costs, the Intermediary excluded the time spent by residents on research and other scholarly activities, as the research rotations did not involve patient care. The negative reimbursement impact of this exclusion was approximately $428,626.

FN1. As the question at issue here is quite narrow, the Court does not discuss the statutory and regulatory scheme of Medicare in detail. An in-depth discussion of that scheme is provided in the R & R.

Plaintiff appealed to the Provider Reimbursement Review Board. The Board ruled in favor of Plaintiff, finding that the regulation did not exclude resident research time or require research time to be connected to patient care. On June 7, 2005, the Administrator reversed the Board's decision, and Plaintiff appealed the Administrator's final decision to this Court.

Magistrate Judge Velasco concluded that the Administrator's final decision was based on an impermissible construction of the Medicare statute, and that the resident research time should be included. For the reasons stated below, the Court agrees.

II. LEGAL ANALYSIS

A. STANDARD OF REVIEW

The District Court conducts a de novo review of those part of an R & R to which objections are filed. 28 U.S.C. § 636(b); Fed.R.Civ.P. 72(b). The District Court may either accept, reject, or amend all or any portion of the R & R. *Id.*If the parties do not object to the R & R or portions thereof, the Court will not modify or set aside those portions unless they are clearly erroneous or contrary to law. *See*28 U.S.C. § 636(b)(1); Fed.R.Civ.P. 72; *Johnson v. Zema Systems Corp.*, 170 F.3d 734, 739 (7th Cir.1999); *Conley v. Crabtree*, 14 F.Supp.2d 1203, 1204 (D.Or.1998).

An agency's construction of the statute it administers is generally governed by *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). If Congress's intent is clear, then the Court must effect to the unambiguously expressed intent of Congress. *Id.* at 842-43.If the Court finds that the statute is ambiguous, then the Court must determine whether

the agency's interpretation is based on a permissible construction of the statute.*Id.* at 843.The Court defers to the agency's judgment unless the statutory text "unambiguously forbids" the agency's view. *Barnhart v. Walton*, 535 U.S. 212, 218 (2002). The agency's interpretation need not be the only reasonable interpretation or even the best interpretation. *Conn. Dep't of Income Maint. v. Heckler*, 471 U.S. 524, 532 (1985); *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). The agency's interpretation is entitled to controlling weight if it falls "within the bounds of reasonable interpretation."*Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 453 (1999).

B. DISCUSSION

***2** Defendant objects to the Magistrate Judge's conclusion that the regulation is unambiguous and the Agency's interpretation of the regulation is impermissible. Defendant argues that the regulation is ambiguous, and the Agency's interpretation is reasonable and permissible.

According to the relevant information, a resident must be assigned to "the portion of the hospital subject to the prospective payment system" or to the outpatient department in order to be included in IME. 42 C.F.R. § 412.105(f)(1)(ii)(A) (1999). At issue here is the meaning of the word "portion." Plaintiff contends that "portion" is a geographical term, and thus all residents assigned to the hospital are included. Defendant argues that "portion" is an ambiguous term which implies, or can be construed to imply, a direct patient care requirement. The residents at issue, while working in the geographic "portion of the hospital subject to the prospective payment system," were not working directly in patient care. The Magistrate Judge agreed with Plaintiff, and concluded that "portion" is a geographical term.

In its review of a nearly identical regulation,[FN2] the Ninth Circuit held that the limitation was unambiguously geographical. *Alhambra Hosp. v. Thompson*, 259 F.3d 1071, 1073-73 (9th Cir.2001). Because the limitation was purely geographical, the Secretary's construction of the regulation was impermissible. *Id.* The Court agrees with this conclusion. It is clear from the plain meaning of the phrase "portion of the hospital subject to the prospective payment system" that the term is geographic in nature. As the IME regulation is unambiguous, the Agency's interpretation in this instance is owed no deference. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). The resident research time should be included in Plaintiff's 1998 and 1999 IME FTE calculations.

> FN2. The statute involved the word "area" as opposed to "portion." *Alhambra Hosp.*, 259 F.3d at 1073-75. This slight difference is not sufficient basis for distinguishing it from the present case.

Accordingly,

IT IS ORDERED that the Report and Recommendation of the Magistrate Judge, filed February 15, 2007, (Doc. No. 38) is **ADOPTED.**

IT IS FURTHER ORDERED that Defendant's Motion for Summary Judgment (Doc. No. 19) is **DENIED.**

IT IS FURTHER ORDERED that Plaintiff's Motion for Summary Judgment (Doc. No. 23) is **GRANTED.**

IT IS FURTHER ORDERED that this cases is **REMANDED** to the Secretary for proceedings consistent with this order.

IT IS FURTHER ORDERED that Defendant pay Plaintiff interest on the payments resulting from this Order in accordance with 42 U.S.C. § 1395oo(f)(2).

REPORT AND RECOMMENDATION

BERNARDO P. VELASCO, United States Magistrate Judge.
Pending before the court are cross motions for summary judgment pursuant to Fed. R.Civ.P. 56(b) and Rule 56.1 of this Court filed by the plaintiff, University Medical Center Corporation, and the defendant, Michael O. Leavitt, Secretary of the Department of Health and Human Services. The motions are fully briefed and ripe for disposition.

On September 22, 2005, this case was randomly referred to Magistrate Judge Bernardo P. Velasco. On November 15, 2006, the Magistrate Judge heard oral argument on the cross motions. (Document # 's 19, 23). There being no genuine issue as to any material

fact, for reasons which follow, the Magistrate Judge recommends that the District Court DENY Defendant's Motion for Summary Judgment and GRANT Plaintiff University Medical Center Corporation's Cross-Motion for Summary Judgment.

BACKGROUND

***3** This civil action arises out of Defendant's failure to reimburse Plaintiff amounts due under the Medicare program of the Social Security Act, 42 U.S.C. § 1395*et seq.*, as determined by a "proxy" formula add-on to the prospective payment system, for the 1998-1999 fiscal years. The amount in dispute relates to Plaintiff's indirect medical education ("IME") costs for the training of medical school graduates assigned to participate in scholarly research.

I. Governing Statutes and Regulations

Medicare is a federal health insurance program funded by the federal government and established in 1965 to provide health insurance to the aged and disabled. 42 U.S.C. § 1395*et seq.* The United States Department of Health and Human Services ("HHS") administers the Medicare program through its component Centers for Medicare and Medicaid Services [FN1] ("CMS"). Hospitals that provide services to Medicare patients are reimbursed for their expenses under Title XVII of the Social Security Act, 42 U.S.C. § 1395*et seq.*Part A of the Medicare Act authorizes payment to participating hospitals ("providers") for their direct and indirect costs of providing inpatient care to beneficiaries. 42 C.F .R. § 413.9(a), (b). Medicare also reimburses teaching hospitals for the costs of graduate medical education, including physician time for instructing and supervising interns and residents. 42 U.S.C. § 13952ww(h).

> FN1. Formerly known as the Health Care Financing Administration.

Medicare services are furnished by "providers of services" that have entered into provider agreements with the Secretary of the United States Department of Health and Human Services. 42 U.S.C. § 1395x(u), 1395cc. To receive payment from the Secretary, providers are required to comply with the provider agreement, as well as all Medicare statutes and regulations. 42 U.S.C. § 1395cc(b)(2).

The Secretary contracts with fiscal intermediaries, such as Blue Cross Blue Shield Association in the instant case, to audit the costs submitted by Medicare provider hospitals and approve or disapprove Medicare reimbursement. See 42 U.S.C. § 1395h; 42 C.F.R. 405.902 (defining fiscal intermediary).

A provider dissatisfied with the intermediary's final determination of total reimbursement may file an appeal with the HHS's Provider Reimbursement Review Board ("RRB").42 U.S.C. § 1395oo(a); 42 C.F.R. § 405.1835. The PRRB is authorized to hold a hearing on the appeal and issue a decision. *Id.* A party may appeal the PRRB's decision to the Secretary's delegate, the Administrator of CMS. 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. 405.1875. If the CMS Administrator decides to review the case, he or she may affirm, reverse, modify or remand the PRRB's decision. 42 C.F.R. § 405.1875. The final decision of the PRRB, or of the CMS Administrator if he or she exercises the right of review, is subject to judicial review. 42 U.S.C. § 1395oo(f)(1).

From its inception, Medicare reimbursed hospitals for the actual costs of treating Medicare patients, subject to a reasonable-cost limitation. The Medicare Act defines "reasonable cost" as "the cost actually incurred," less any costs "unnecessary in the efficient delivery of needed health services."42 U.S.C. § 1395x(v)(1)(A).

***4** In 1983, Congress amended the Medicare Act and established a prospective payment system for reimbursing inpatient operating costs of acute care hospitals. See 42 U.S.C. § 1395ww(d). Hospitals now are reimbursed on the basis of prospectively determined national and regional rates for each discharge, rather than on the basis of retrospectively determined reasonable costs incurred. Under this system, payment is made at a predetermined rate for each hospital discharge, according to the patient's diagnostic related group ("DRG"). Congress intended this method of payment to encourage hospitals to increase efficiency. See H.R.Rep. No. 98-25, at 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351.

When Congress implemented the DRG system, it was concerned that those payments would not adequately reimburse teaching hospitals because such hospitals typically have higher costs per patient than

non-teaching hospitals. S.Rep. No. 98-23, at 52 (1983), reprinted in 1983 U.S.C.C.A.N. 143, 192; H.R.REp. No. 98-25, at 140 (1983), reprinted in 1983 U.S.C.C.A.N. 219, 359. Thus, the DRG payment-calculated on average per-patient costs in a particular region-would not reflect teaching hospitals increased expenses. The prior reimbursement system also had this problem because the reasonable-cost limitations it used were similarly calculated, though not on a prospective basis. Under the prior system, Congress had allowed adjustments to the reasonable-cost limitations if a provider could show its increased costs were due to its educational activities. Under the new system, Congress carried forward the policy of paying teaching hospitals more, allowing their increased expenses to be separately reimbursed by Medicare. Three types of increased costs were identified: direct medical education ("DME") expenses, capital expenses, and indirect medical education ("IME") expenses. DME expenses are expenses like residents' salaries-quantifiable expenses directly related to teaching. Capital expenses are those expenses like depreciation and rents. And IME expenses reflect the general inefficiencies associated with patient care provided by residents and interns, including "the additional tests and procedures ordered by residents as well as the extra demands placed on other staff as they participate in the educational process."*Id.*

IME expenses are not easily quantified. So the Secretary created a formula to calculate how much money teaching hospitals would get for IME expenses. That formula-derived from a statistical analysis of teaching hospitals' costs compared to non-teaching hospitals' costs that takes into account the ration of residents and interns to beds, 45 Fed.Reg. 21,584 (Apr. 1, 1980)-basically allows teaching hospitals to get a payment that represents a fraction of their DRG revenue. For example, if the Secretary's formula-which is now codified in 42 U.S.C. § 1395ww(d)(5)(B)-yields an "indirect teaching adjustment factor" of .10, then a teaching hospital that has $10,000 of DRG revenue in a given cost reporting period (i.e., fiscal year) would get an additional payment of $1,000 as reimbursement for IME expenses.

***5** In 2001, after the fiscal years at issue in this case, the Secretary promulgated a regulation designed to "clarify" and remove confusion in the provider community, regarding "whether the time that residents spend performing research is countable" for purposes of IME adjustment. 66 Fed.Reg. 39,828, 39, 896 (Aug. 1, 2001). The rule explicitly provides that, in isolating the "portion of the hospital subject to the prospective payment system,"42 C.F.R. § 412.105(f)(1)(ii)(a), and the "outpatient department," 42 C.F.R. § 412.105(f)(1)(ii)(B), the time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. § 412.105(F)(1)(iii)(B).

II. Factual and Procedural History

Plaintiff University Medical Center ("Plaintiff" or "Hospital") is an acute-care, non-profit hospital located in Tucson, Arizona. In affiliation with the University of Arizona Health Sciences Center, the Hospital operates a graduate medical education program for interns and residents in 37 specialties and subspecialty areas. The program involves interns and residents in patient care and residents generally "rotate" through a number of planned training areas in connection with their specialization area. The Hospital participates in the federal governments Medicare program and submitted Medicare cost reports for its 1998 and 1999 fiscal years ("FY").

The residency programs at issue in this case are approved by the Accreditation Council for Graduate Medical Education ("ACGME"), an organization recognized by the Center for Medicare & Medicaid Services ("CMS") as an acceptable authority for determining which graduate medical education programs are "approved" for purposes of the Medicare program and the indirect medical education payment regulations.

The ACGME generally requires that in order for a given residency program to be "approved," the program must ensure that residents and faculty participate in "research and scholarly activity." Residents in the Hospital's approved residency program are required to participate in research activities in order to obtain their specialty or subspecialty certifications.

For purposes of completing its Medicare cost reports for FY 1998 and 1999, the Hospital included the time spent by residents engaged in research and other scholarly activities who were assigned to the Hospital

when determining its resident count for purposes of the IME calculation.

Blue Cross Blue Shield Association ("Association") is the Hospital's fiscal intermediary under a contract with the Secretary. In the region where the Hospital is located, the Association subcontracted its Medicare payment administration duties to Blue Cross Blue Shield of Arizona ("BCBSA") (the Association" and BCBSA are collectively referred to herein as the "Intermediary").

After its audit, the Intermediary adjusted the Hospital's 1998 and 1999 FY IME payments to reflect an exclusion of time spent by residents engaged in the research and other scholarly activities portions of their approved residency programs from the IME calculation. The Intermediary's justification for removing this time was that the residents in research rotations were not "involved in usual patient care." This adjustment resulted in a loss of 10.06 full time equivalent ("FTE") residents for 1998 and 4.96 FTE residents for 1999. The negative reimbursement impact of this disallowance to the Hospital is approximately $428,626.

***6** The Hospital timely appealed its FY 1998 and 1999 cost reports to the Provider Reimbursement Review Board ("PRRB"), appealing the Intermediary's disallowance of resident time spent in research and other scholarly activities. After an in-person hearing on January 15, 2005, the PRRB held in favor of the Hospital on this issue, finding that the regulation for the relevant time period did not exclude resident research time from the IME resident count, and did not require resident time be related to patient care. The PRRB also stated that the 2001 amendment to the IME regulation purporting to exclude non-patient care research time from the resident count "represents a change in policy that cannot be applied retroactively to the subject 1998 and 1999 cost reporting periods."

On June 7, 2005, the CMS administrator reversed the PRRB's decision.

Having exhausted its administrative remedies, the Hospital timely appealed the Administrator's final decision, pursuant to its rights under Section 1878(f) of the Social Security Act and 42 C.F.R. § 405.1877.

DISCUSSION

I. Plaintiff's Position

The historical purpose and design of the IME payment, together with the plain language of the statute and applicable regulations, compel the legal conclusion that residents in approved graduate medical education programs who are assigned to a certain hospital must be included in that hospital's count of residents regardless of the nature of their training activities. See 42 U.S.C. § 1395ww(d)(5)(B); 42 C.F.R. § 412.105(f)(1)(1998 & 1999).

II. Defendant's Position

The regulation that was in effect at the times relevant to this case limited the FTE count to those hours where the student doctors were assigned to the "portion of the hospital subject to the prospective payment system,"42 C.F.R. § 412.105(f)(1)(ii)(A) (1999), or to the "hospital outpatient department." 42 C.F.R. § 412.105(f)(1)(ii)(B)(1999). Because assignment to the area of scholarly research does not fall within either category, the "time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient" could reasonably be excluded from the FTE count, 42 C.F.R. § 412.105(f)(1)(iii)(B), as the regulations now provide expressly.

III. Standard of Review

The final decision of the Secretary is reviewed under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq. 42 U .S.C. § 1395oo(f)(1) (incorporating the APA standard of review). Under the APA, the Secretary's decision is set aside if it is arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law. 5 U.S.C. § 706(2).*See* *Pacific Coast Medical Enterprises v. Harris*, 633 F.2d 123, 130 (9th Cir.1980); *Good Samaritan Hospital, Corvallis v. Mathews*, 609 F.2d 949, 951 (9th Cir.1979).

An agency's construction of the statute it administers is generally governed by *Chevron U.S.A., Inc. v. Natural Res.Def. Council, Inc.*, 467 U.S. 837 (1984). First, the court must review the agency's construction of the statute to determine if the intent of Congress is clear, and, if so, give effect to the unambiguously expressed intent of Congress. *Chevron*, 467 U.S. at

842-43. If the court determines that Congress has not directly addressed the precise question at issue, the court must determine whether the agency's interpretation is based on a permissible construction of the statute. *Id.* at 843.Administrative interpretations which are contrary to clear congressional intent must be rejected. *Id* at n. 9.

***7** When reviewing the Secretary's construction of a Medicare statute under the standard in *Chevron, Id.*, the Court must defer to the Secretary's judgment unless the statutory text "unambiguously forbids" his view or his interpretation "exceeds the bounds of the permissible" for other reasons.*Barnhart v. Walton*, 535 U.S. 212, 218 (2002). To meet this test, the Secretary's reading "need not be the only reasonable one,"*Conn. Dep't of Income Maint. v. Heckler*, 471 U.S. 524, 532 (1985), or even "the best or most natural one by grammatical or other standards."*Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). Rather, his construction is entitled to controlling weight so long as it falls "within the bounds of reasonable interpretation."*Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 453 (1999).

The task of a court reviewing the Secretary's reading of his own regulations "is not to decide which among several competing interpretations best serves the regulatory purpose,"*Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994), but rather "the agency's interpretation must be given'controlling weight unless it is plainly erroneous or inconsistent with the regulation."*Id.* (quoting *Bowles v. Seminole Rock & Sand Col* ., 325 U.S. 410, 414 (1945)).

IV. Analysis

A. The Secretary's Decision and the Plain Language of the IME Regulation.

Plaintiff argues that Congress has spoken directly on this issue, given the plain language of 42 U.S.C. § 1395ww(d)(5)(B), which dictates that "the Secretary shall proved [the IME payment] in an amount computed in the same manner as the adjustment for such costs under regulation in effect as of January 1, 1983," except as modified by Congress.

The Secretary has adopted regulations incorporating the various Congressional IME enactments. The Secretary's regulations detail the steps necessary to calculate the Congressionally mandated equation, which is summarized as follows:

[{ 1 ⟸ (R/B) } n-1] x c = "IME Adjustment Factor"

In the equation, "R" equals the hospital's full-time equivalent interns and residents; "B" equals the number of the hospital's beds; "n" is the "teaching activity" factor of .405; and "c" is an adjustment factor set by statute. See 42 U.S.C. § 1395ww(d)(5)(B)(ii).

In his regulations, the Secretary defines "n" as the "factor representing the effect of teaching on inpatient operating costs ..."42 C.F.R. § 412.105(c). This teaching activity factor is not applied to the costs of services but to the size of the residency training program as measured by the resident to bed ratio.

The interpretation at issue is located at 42 C.F.R. § 412.105(f)(1), which states, in relevant part:

(1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent resident for the purpose of determining the indirect medical education adjustment is determined as follows:

***8** (i) The resident must be enrolled in an approved teaching program.

...

(ii) In order to be counted, the resident must be assigned to one of the following areas:

(A) The portion of the hospital subject to the prospective payment system.

(B) The outpatient department of the hospital.

42 C.F.R. § 412.105(f)(1)(i)-(ii). In addition, "full time equivalent status is based on the total time necessary to fill a residency slot."

Plaintiff submits that the Hospital's residents met both of the regulatory requirements for inclusion in the Hospital's IME FTE resident count: 1) The residents were enrolled in approved teaching programs, and 2) The residents were "assigned to" the PPS or outpatient departments of the hospital.

Defendant argues that the authorizing statute cannot reasonably be construed as prohibiting the Secretary from excluding scholarly research from the FTE count. As of January 1, 1983, there were no regulations published in the CFR that established an FTE count pursuant to 42 U.S.C. § 1395ww(a)(2) at all. So long as research time could have been permissibly excluded from the FTE count used for purposes of the IME adjustment applied under a reasonable construction of the old cost-limit regime, that outcome is "within the bounds of reasonable interpretation" here.

Defendant further argues that the language of the regulation requiring assignment of interns or residents to a "portion of the hospital subject to the prospective payment system,"42 C.F.R. § 412.105(f)(1)(ii)(A)(1999) can plausibly read to exclude assignment to the area of scholarly research for the reason that the costs of research are not subject to being reimbursed by the prospective payment system.

Defendant asserts that the issue in this case comes down to a question of what it means to say that a resident or intern has been assigned to the "portion of the hospital subject to the prospective payment system."Defendant argues that "portion" means a "share" or "a part of any whole, either separated from or integrated from or integrated with it,"*citing Random House Webster's Unabridged Dictionary* 1507 (2d ed.2001). From this, it follows that the "portion" of the hospital, in turn, that is "subject to" payment under "the prospective payment system" is that portion wherein, at any given moment, "covered hospital inpatient services" are "furnished to beneficiaries." 42 C.F.R. § 412.20(a). Thus, Defendant urges, the share of the hospital subject to PPS logically excludes any portion wherein any activities other than the furnishing of patient-care services are being conducted.

Plaintiff argues that this regulation was properly analyzed by the court in *Riverside Methodist Hospital v. Thompson,* 2003 U.S. Dist. LLEXIS 15163. The Secretary's attempt to read a patient care requirement into the regulation was specifically addressed and denied by the Southern District of Ohio in *Riverside Methodist.* 2003 U.S.Dist. LEXIS at * 14-15.

***9** Defendant submits that the decision in *Riverside Methodist* (on which the PRRB relied) came to a contrary conclusion only by failing to follow its own line of reasoning to its logical conclusion. Where the decision went wrong, Defendants argue, was in failing to take the analysis one step further and examine what it means-in light of the entire Medicare statutory and regulatory scheme developed over the last four decades-for a resident to be said to be "assigned" to a "portion of the hospital subject to the prospective payment system."When that analysis is undertaken, it becomes clear that there was never any need for the Secretary to impose any additional requirement related to "providing care for specific patients" in order to exclude research time from the FTE count. The mistake made by the *Riverside Methodist* court was to assume, without analysis, the very question that was in dispute: whether a student doctor is assigned to a portion of the hospital subject to PPS or to the outpatient department when he is assigned to the area of scholarly research.

The Magistrate Judge agrees with the reasoning and decision of the District Court in *Riverside Methodist.*The regulation is not ambiguous, and, when considered in context with the historical intent of both the regulation and its governing statute, it is evident that all time spent by residents in research and other scholarly activities while they are "assigned to" the Hospital must be included when determining the Hospital's resident count for purposes of calculating the IME payment.

The Defendant's argument that the term "portion," as used in the regulation, implies a "direct patient care" requirement, is successfully refuted by the Ninth Circuit's interpretation of a nearly identical regulation in *Alhambra Hospital v. Thompson,* 259 F.3d, 1071, 1073-75 (9th Cir.2001).

Further, it is clear from the plain meaning of the phrase "portion of the hospital subject to the prospective payment system" in 42 C.F.R. § 412.105(f)(i), that the term is geographic in nature.

Thus, the Magistrate Judge finds that, the IME regulation being unambiguous, the Secretary's interpretation in this instance is owed no deference. *Thomas Jefferson,* 512 U.S. at 512.

B. Retroactivity and Rulemaking

Plaintiff submits that the Secretary has imposed substantive requirements upon the Hospital in violation of the APA's rulemaking requirements by holding that only time directly related to patient care can be included in the Hospital's FTE resident count.

Plaintiff also submits that the Secretary has retroactively applied the August 1, 2001 change in the IME regulation to the Hospital's 1998 and 1999 cost reports, in violation of section 551 of the APA.

As summarized by the Defendant in this case, if the Secretary has construed his regulation permissibly, then he has not created any new substantive rule. If he has not construed his regulation permissibly, then it does not matter whether the erroneous reading is characterized as substantive or interpretive. The Plaintiff concedes that the resolution of this issue is not necessary for a decision favorable to the Hospital in this case.

***10** As the Magistrate Judge finds the Defendant has not construed his regulations permissibly, a recommendation as to the retroactivity and rulemaking arguments is not necessary to resolve the issue in this case.

V. Recommendation

The Magistrate Judge recommends that the District Court, DENY Defendant's Motion for Summary Judgment (Doc. No. 19.) and GRANT Plaintiff University Medical Center Corporation's Cross-Motion for Summary Judgment (Doc. No. 23.)

Pursuant to Title 28 U.S.C. § 636(b), any party may serve and file written objections within 10 days of being served with a copy of this Report and Recommendation. If objections are not timely filed, they may be deemed waived. If objections are filed, the parties should use the following case number: CIV 05-495-TUC-JMR.

D.Ariz.,2007.
University Medical Center Corp. v. Leavitt
Slip Copy, 2007 WL 891195 (D.Ariz.), Med & Med GD (CCH) P 302,057

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further proceedings in accordance with this opinion.

[¶ 301,341] Riverside Methodist Hospital v. Thompson.

S. D. Ohio, No. C2-02-94, July 31, 2003.

Medicare: IME Adjustment

Provider reimbursement—Allowable costs—Cost of educational activities.—CMS improperly reduced the hospital's indirect medical education (IME) payment by excluding hours spent by residents on activities unrelated to direct patient care. The Secretary interpreted the applicable regulation concerning IME reimbursement, 42 C.F.R. § 412.105, as allowing only direct patient care to be included in the IME resident full-time equivalent cost calculation, not time the residents spent on other activities required by the program such as journal club, obstetrics/gynecology seminars and psychiatry seminars. The regulation does not include a requirement that only resident hours spent in providing actual patient care can be included for purposes of the IME full time equivalent resident count. The hospital was in compliance with the regulation because its residents were (1) enrolled in an approved teaching program, which was accredited by an organization that requires residents to participate in educational, non-direct care activities similar to the hospital's program, and (2) assigned to a portion of the hospital subject to the PPS or to the outpatient department of the hospital. Therefore, the hospital was entitled to IME payment for hours residents spent on activities unrelated to direct patient care.

See ¶ 4260.

[Text of Decision]

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO

Riverside Methodist Hospital, Plaintiff vs Tommy G. Thompson, Secretary of Health and Human Services Defendants

JUDGMENT IN A CIVIL CASE

Case Number C2-02-94

Judge Holschuh Magistrate Judge King

[] **Jury Verdict.** This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

[] **Decision by Court.** This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

[x] **Decision by Court.** This action was decided by the Court without a trial or hearing.

IT IS ORDERED AND ADJUDGED that pursuant to the Memorandum and Order of July 31, 2003, JUDGMENT is entered reversing the decision of the Secretary and REMANDING the case to the Provider Reimbursement Review Board for a determination of the appropriate amount of reimbursement, together with interest thereon provided by U.S.C. § 1395oo(f)(2) and for further proceedings consistent with this Opinion.

Date: July 31, 2003

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

RIVERSIDE METHODIST HOSPITAL, Plaintiff, v. TOMMY G. THOMPSON, Secretary of Health and Human Services, Defendant.

Case No. C2-02-94

Judge Holschuh Magistrate Judge King

MEMORANDUM AND ORDER

Plaintiff Riverside Methodist Hospital ("Riverside") seeks judicial review, pursuant to 42 U.S.C. § 1395oo, of a decision by the Defendant Secretary of Health and Human Services ("Secretary") denying Medicare reimbursement for certain costs incurred by Riverside during its fiscal year ending June 30, 1996. The crux of this case involves the validity of the Secretary's interpretation and application of a particular Medicare regulation, 42 C.F.R. § 412.105.[1] The parties have agreed this current issue can be resolved as a matter of law on the parties' cross motions for summary judgment. (Docket Nos. 8 and 11).[2]

I. Background

A. Statutory and Regulatory Background

Congress created Medicare in 1965 to serve as a federally funded and administered health insurance program for the elderly and the disabled. 42 U.S.C. § 1395 *et seq.* Pursuant to congressional authorization, the Secretary has promulgated ex-

[1] Unless otherwise noted, all citations to the Code of Federal Regulations are to the 1995 version, which was the version in effect at the end of Riverside's 1996 fiscal year.

[2] Plaintiff has requested oral argument in this case; however, the Court finds that oral argument would not further aid in the determination of the legal issues involved in this case. Accordingly, Plaintiff's request is denied, and the Court will decide the matter on the briefs submitted.

tensive regulations governing the administration of the Medicare program. The Secretary has delegated responsibility for administering the Medicare program to the Administrator of the Centers for Medicare & Medicaid Services ("CMS Administrator" or "Administrator"). Hospitals, including Riverside, enter into written agreements with the Secretary to be "providers of services" for eligible individuals under the Medicare Act. 42 U.S.C. §1395cc. Under the Medicare program, the government pays for specific medical services rendered by participating providers to Medicare beneficiaries. The process of reimbursing Medicare service providers is conducted through "fiscal intermediaries" who contract with, and serve as agents for, the Secretary.[3]

At the end of each fiscal year, a provider is required to file a Medicare cost report with its fiscal intermediary; the fiscal intermediary then analyzes the report and issues a Notice of Program Reimbursement ("NPR") identifying the amount of Medicare payment that it determines is due to the provider for that period. 42 C.F.R. §405.1803. If the provider is dissatisfied with the amount determined by the fiscal intermediary, it may request a hearing before the Provider Reimbursement Review Board ("PRRB" or "Board"). 42 U.S.C. §1395oo(a). The PRRB's decision is final unless the Secretary, acting through the CMS Administrator, reverses, affirms, or modifies the Board's decision within 60 days. 42 U.S.C. §1395oo(f)(1); 42 C.F.R. §§405.1871(b) and 405.1875(a). Providers may seek judicial review of any final decision of the Board, or of any reversal, affirmance, or modification of the Board's decision by the Administrator if the Administrator decided to exercise his or her power of review. 42 U.S.C. §1395oo(f)(1); 42 C.F.R. §405.1877.

In the current case, the dispute arises from the calculation and determination of a certain reimbursement amount to which Riverside alleges it is entitled for "indirect medical education" (or "IME") costs associated with one of its graduate medical education programs. It is therefore important, at the outset, to summarize the mechanism by which indirect medical education costs are reimbursed under the Medicare program.

B. Reimbursement for Indirect Medical Education Costs

Prior to 1983, hospitals received reimbursement for medical services provided to Medicare beneficiaries on a "reasonable cost" basis. "Reasonable cost" equaled the actual cost incurred by the hospital minus any cost found to be unnecessary or excessive. 42 U.S.C. §1395x(v). Under this system, reimbursement was retroactive and, because reimbursement was tied to actual cost, there was little incentive for hospitals to provide covered services in an efficient, cost-effective manner. In order to provide such an incentive, Congress enacted the Prospective Payment System ("PPS") in 1983, pursuant to which providers were reimbursed based on predetermined federal rates rather than on the actual costs of the services provided. 42 U.S.C. §1395ww. If hospitals were able to provide a given service for less than the federal reimbursement rate, they would keep the excess; on the other hand, if hospitals spent more than the federal rate when providing covered services, they would suffer a loss on the transaction. Consequently, the PPS gave hospitals an economic incentive to operate efficiently when providing Medicare services.

Congress recognized, however, that "teaching hospitals" typically have higher operating costs in providing patient services than non-teaching hospitals. The reasons for these increased costs were said to include:

> the severity of illness of patients requiring the specialized services and treatment programs provided by teaching institutions and the additional costs associated with the teaching of residents. The latter costs are understood to include the additional tests and procedures ordered by residents as well as the extra demands placed on other staff as they participate in the educational process.

H.R. Rep. No. 98-25(I) (1983), reprinted in 1983 U.S.C.C.A.N. 219, 359. Under the "reasonable cost" system, reimbursement for these higher costs was determinable, because the reimbursement was tied to actual costs. Under the PPS system, however, the generally applicable predetermined federal rates did not take into consideration these higher costs, and hence would leave teaching hospitals experiencing a shortfall. Given that the PPS rates would not, by themselves, compensate teaching hospitals for these increased costs, Congress enacted what it called the "indirect medical education" adjustment ("IME") in order to bring the reimbursements to the appropriate level for those institutions. 42 U.S.C. §1395ww(d)(5)(B).[4] However, these "indirect costs" were not separately identifiable or easily quantified, so Congress chose to statistically estimate these costs as a function of so-called "teaching intensity" – the theory being that the more a hospital engages in educational programs, the higher its IME costs will be. 51 Fed. Reg. 16772,

[3] The fiscal intermediary serving Riverside during the relevant time period in this case was Blue Cross and Blue Shield Association/AdminaStar Federal.

[4] The "direct" costs of a graduate medical education program are reimbursed under a separate statutory mechanism known as "GME." 42 U.S.C. §1395ww(h); 42 C.F.R. §413.86. The IME adjustment, unlike payments under GME, is a result of the PPS, and is simply designed to account for the increased operating costs experienced by teaching hospitals in the care and treatment of patients in teaching hospitals (the so-called "indirect" costs of medical education) and is not designed to reimburse the direct costs of operating a graduate medical education program.

16775; *University of Kentucky v. Shalala*, 858 F. Supp. 639, 641 (E.D. Ky. 1994). "Teaching intensity" is expressed as a ratio of full-time equivalent residents and interns (hereinafter referred to collectively as "FTE residents") to the number of available beds in the hospital. *Id.*; 42 C.F.R. §412.105. In the governing statute, this "teaching intensity" is incorporated in a formula used in the process for a determination of the amount of reimbursement for IME costs, *i.e.* c × (((1 + r) to the nth power) − 1) where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds, "n" equals .405, which is the factor representing the effect of teaching activity on inpatient operating costs, and "c" is equal to various statutory amounts for different fiscal year periods. 42 U.S.C. § 1395ww(d)(5)(B)(ii).

C. Procedural History of This Case

Riverside operates a large, non-profit hospital with a teaching program. Its graduate medical education program for interns and residents is reviewed and accredited by the Accreditation Council for Graduate Medical Education ("ACGME"), and is thus approved to operate residency programs in various specialties, including the specialty of family practice. In fiscal year 1996, Riverside had 18 residents enrolled in the family practice residency program.

The following activities were among those included in Riverside's family practice residency program: Journal Club (first-year rotation); OB/GYN seminars (second-year rotation); and psychiatry seminars (third-year rotation). All of these activities were required components of the family practice residency program under ACGME standards.

On July 31, 1997, Riverside's fiscal intermediary, AdminaStar Federal, issued a Notice of Amount of Program Reimbursement following an audit of Riverside's cost report for fiscal year 1996. (A.R. at 529-55).[5] The Intermediary made a downward adjustment to Riverside's FTE resident count for purposes of its claimed IME reimbursement by excluding hours spent by residents in journal club, practice management seminars, ob/gyn seminars, and psychiatric seminars. (A.R. at 292-93, 339-43). The Intermediary excluded these hours because they were not related to "hands-on patient care." (A.R. at 302). Riverside appealed the Intermediary's decision to the PRRB. (A.R. at 541-55). On September 26, 2001, the PRRB found in favor of Riverside and reversed the Intermediary's adjustment to the FTE resident count, noting that "there is no authority in support of the Intermediary's contention that the activities performed by the residents be directly related to hands-on patient care." (A.R. at 38).

On October 12, 2001, the Director, Division of Acute Care in the Center for Medicare Management, CMS, requested that the Administrator review the PRRB's decision regarding the proper calculation of FTE residents for purposes of IME payments. (A.R. at 23-27). On November 14, 2001, the Administrator reversed the PRRB's decision, and held that the hours spent in the disputed activities were not to be included when calculating the FTE resident count for purposes of IME. (A.R. at 11-16). The Administrator stated that "'the indirect costs of medical education incurred by teaching hospitals are the increased operating costs (that is patient care costs) that are associated with approved intern and resident programs,' " and concluded that the residents' hours at issue were not "related to patient care", and therefore should be disallowed. (A.R. at 14-16). The Administrator's decision constituted the final administrative decision of the Secretary, and Riverside filed a timely appeal to this Court. 42 U.S.C. § 1395oo(f)(1).

II. Standard of Review

Judicial review of a decision of the Secretary is governed by 42 U.S.C. § 1395oo(f), which incorporates section 706 of the Administrative Procedure Act, 5 U.S.C. § 706. Under section 706, the relevant question before the court is whether the administrative decision was arbitrary and capricious, contrary to law, or unsupported by substantial evidence. *Maximum Home Health Care, Inc., v. Shalala*, 272 F.3d 318, 320 (6th Cir. 2001). An agency's interpretation of its own regulation is entitled to deference "unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994) (citations and internal quotations omitted). With this standard in mind, the Court now turns to the parties' cross motions for summary judgment.

III. Discussion

A. The Plain Language of 42 C.F.R. §412.105(g)

Riverside contends that the Secretary's determination of the hospital's IME FTE resident count for fiscal year 1996 is contrary to the plain language of the governing regulation at issue and therefore cannot stand. Specifically, Riverside argues that the regulation clearly contains no mention of any requirement that resident hours be counted for IME purposes only if they are related to "patient care."

Section 412.105(g) of the Medicare regulations, reads in pertinent part:

[5] "A.R." refers to the Administrative Record filed in this case.

Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.

(1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent residents for the purpose of determining the indirect medical education adjustment is determined as follows:

(i) *The resident must be enrolled in an approved teaching program.* An approved teaching program is one that meets one of the following requirements:

(A) Is approved by one of the national organizations listed in § 405.522(a) of this chapter.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the Directory of Residency Training Programs published by the American Medical Association.

(C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(ii) *In order to be counted, the resident must be assigned to one of the following areas:*

(A) The portion of the hospital subject to the prospective payment system.

(B) The outpatient department of the hospital.

(C) For discharges occurring on or after August 10, 1993, any entity receiving a grant under section 330 of the Public Health Service Act that is under the ownership or control of the hospital (if the hospital incurs all, or substantially all, of the costs of the services furnished by those residents).

(iii) *Full-time equivalent status is based on the total time necessary to fill a residency slot.* No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of time worked in any of the areas of the hospital listed in paragraph (g)(1)(ii) of this section, to the total time worked by the resident. A part-time resident or one working in an area of the hospital other than those listed under paragraph (g)(1)(ii) of this section (such as a free-standing family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (g)(1)(ii) of this section, compared to the total time necessary to fill a full-time internship or residency slot.

(2) To include a resident in the full-time equivalent count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

(i) A listing, by specialty, of all residents *assigned* to the hospital and providing services to the hospital during the cost reporting period.

(ii) The name and social security number of each resident.

(iii) The dates the resident is *assigned* to the hospital.

(iv) The dates the resident is *assigned* to other hospitals or other freestanding providers and any nonprovider setting during the cost reporting period.

(v) The proportion of the total time necessary to fill a residency slot that the resident is *assigned to* an area of the hospital listed under paragraph (g)(1)(ii) of this section.

(3) Fiscal intermediaries must verify the correct count of residents.

42 C.F.R. § 412.105(g) (emphasis added).

As Riverside correctly points out, this regulation does not contain, or even implicitly allude to, any requirement that only resident hours spent in providing actual patient care can be included for purposes of the IME FTE resident count. Rather, the regulation provides that a resident is included in the calculation if he or she is (1) enrolled in an approved teaching program, and (2) assigned to a portion of the hospital subject to the PPS or to the outpatient department of the hospital. Importantly, according to the plain language of the regulation, a resident need only be "assigned to" a portion of the hospital subject to the PPS in order to be counted, and no mention is made of a requirement that a resident's time be directly related to providing care for specific patients.[6]

[6] Furthermore, the regulation states that FTE status "is based on *the total time necessary to fill a residency slot*," as opposed to the total time spent providing patient care. 42 C.F.R. § 412.105(g)(1)(iii). As Riverside notes, and as the Secretary effectively concedes, under ACGME standards medical residents are *required* to spend a portion of their time attending seminars and engaging in the type of educational activities involved in this case. (*See* Pl.'s Mot. for Summ. J. at 12). Thus, by requiring residents to be enrolled in an approved educational program, *see* 42 C.F.R. § 412.105(g)(1)(i)(C), the regulation implicitly recognizes that "full-time" residents will spend some of their time engaged in solely educational activities that are not directly related to providing hands-on patient care; yet nothing in the regulation indicates that time so spent should be deducted from the FTE resident count. Although the phrase "total time necessary to fill a residency slot" is not specifically defined in the regulation, it can only reasonably be read to include time spent by residents participating in *required* educational activities (which of course *include*, but certainly are not limited to, activities involving participation in the direct care and treatment of patients), because such activities would be "necessary to fill a residency slot." The Court

Accordingly, the Court concludes that the decision of the PRRB was correct, based upon the following basic and determinative facts and rules of law:

1. It is not denied by the Secretary that Riverside did in fact meet every single requirement of the regulation as it was written at the time in question. The residents were enrolled in an approved teaching program, as required and as defined in §412.105(g)(1)(i); the residents were assigned to one of the areas as required and as listed in §412.105(g)(1)(ii); and Riverside furnished all of the information required and as listed in §412.105(g)(2).

2. It is not denied by the Secretary that the regulation, as it was written at the time in question, does not by its plain language contain any requirement that the time spent by residents had to be spent in direct patient care in order to be counted. The Secretary's argument is that this requirement should be read into the regulation because, in the past, the Secretary has interpreted "indirect costs of medical education" in 42 U.S.C. §1395ww(d)(5)(B) as being "increased costs (that is, patient care costs)," 51 Fed. Reg. at 16775, and "additional operating (that is, patient care) costs," 54 Fed. Reg. at 40286. (Def.'s Mem. in Support of Def.'s Mot. for Summ. J. and in Opp. to Pl.'s Mot. for Summ. J. at 14). While this argument will be discussed in greater detail in the following section of this opinion, it is important to note at this point that: (A) there is nothing ambiguous about the regulation as it has been written; (B) the insertion of a new requirement by the Secretary's "interpretation" of unambiguous language is not legally permissible; and (C) if the Secretary desires to include a new requirement regarding excludable time, it must be done by amendment, and in compliance with the necessary administrative procedures for amending regulations (as was done in 2001 to exclude time spent by residents conducting research).

It is important to note that this is not a case in which a regulatory agency has adopted a challenged regulation dealing with the administration of a statute and which resolves some issue on which the statute is silent or ambiguous. In such cases, the agency's regulation interpreting the statute is given great deference by the courts: *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-845 (1983). In the present case, the agency adopted a regulation as it unquestionably had the power to do, which specifically sets forth the requirements for determining the number of FTE residents a teaching hospital has during a given period of time. Riverside does not challenge that regulation or its application to the statute in question. The challenge, instead, is to the agency's interpretation of its own regulation.

An agency's interpretation of its own regulation is still entitled to deference, but deference is warranted *"only when the language of the regulation is ambiguous." Christensen v. Harris County*, 529 U.S. 585, 588 (2000) (emphasis added). There is certainly nothing ambiguous about §412.105(g)(1). It sets forth two specific requirements—both of which Riverside met—for counting FTE residents for the purpose of determining the ratio of residents to hospital beds as contained in the statutory formula, and also a requirement for specific information to be furnished, which Riverside also met.

To insert a new requirement in the regulation—namely, that in counting the number of FTE residents, a hospital must exclude each and every hour spent by a resident fulfilling the resident's approved program that is not considered by the agency to be spent on individual "patient care"—would be to illegally change the regulation without the necessity of complying with the procedures mandated by the Administrative Procedure Act. 5 U.S.C. §553(b). As the Supreme Court said in *Christensen*, "to defer to the agency's position would be to permit the agency under the guise of interpreting a regulation to create *de facto* a new regulation." 529 U.S. at 588.

The Secretary's "interpretation" of his agency's own regulation in this case does not resolve some ambiguous language in the regulation, nor is a "policy" statement needed to resolve any doubts about the requirements specifically set forth in the regulation. As stated above, to change the regulation and to add a new requirement would require compliance with the Administrative Procedure Act. Notably, this is exactly what the Secretary did in 2001 when the same regulation at issue here was amended to add the requirement that "[t]he time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. §412.105(f)(iii)(B) (2001).

The Secretary contends that this added requirement—the exclusion of research activities—was only a "clarification" of the Secretary's "long-standing policy" that time spent by residents that is not associated with the treatment or diagnosis of a particular patient should be excluded. If, indeed, the Secretary felt it was necessary to incorporate this policy into the regulation, the obvious method would have been to exclude all non-patient care time, and not just non-patient care *research* time;

(Footnote Continued)

need not, however, define the parameters of what exactly is included in the phrase "total time necessary to fill a residency slot" in order to resolve the issue raised by Riverside's appeal. Although the logical interpretation of that phrase buttresses Riverside's argument, the clear and rather obvious answer to the question of whether the FTE resident count is restricted to time spent in the direct care and treatment of patients is found in the undeniable fact that the regulation simply contains no such requirement.

when the regulation was amended.[7] Instead, as Riverside appropriately points out, the addition of this specific exclusion of non-patient care research activity with no reference to any other non-patient care activities (such as the seminars, *etc.*, in question) invokes the statutory canon *expressio unius est exclusio alterius.*

Whether the exclusion added to the regulation in 2001 conflicts with either the Congressional purpose of compensating teaching hospitals for their IME costs, or the statutory method for determining the amount of such compensation, is not an issue in this case. The addition of the research exclusion requirement in the regulation is relevant to this case, however, because it contradicts the Secretary's contention that he need not comply with the Administrative Procedure Act in order to impose another exclusion requirement, this one concerning seminars and similar educational activities, under the guise of "clarification."

B. The Secretary's Interpretation of §412.105(g)(1) is Not Mandated by the Congressional Purpose of Compensating Teaching Hospitals for their IME Costs and the Statutory Formula in 42 U.S.C. §1395ww(d)(4)(B)

1. The Congressional Purpose and the Statutory Formula

As noted earlier, when Congress went from a "reasonable cost" basis to a "prospective payment system" in 1983 as the basis for reimbursement to hospitals for Medicare patients, a problem was created with respect to the increased operating costs in providing patient services in a teaching hospital. While the direct costs of residency programs, *e.g.*, salaries of the residents and other direct costs, could be measured and reimbursed, Congress recognized that there were indirect costs in a teaching hospital that simply could not be accurately or even feasibly measured. As reported by the House of Representatives Ways and Means Committee, these unmeasurable costs are unique to teaching hospitals because of the very nature of those institutions. The inherent costs arise because of:

> factors such as severity of illness of patients requiring the specialized services and treatment programs provided by teaching institutions and the additional costs associated with the teaching of residents. The latter costs are understood to include the additional tests and procedures ordered by residents as well as the extra demands placed on other staff as they participate in the education process. Your committee emphasizes its view that these indirect teaching expenses are not to be subjected to the same standards of 'efficiency' implied under the DRG prospective system, but rather that they are legitimate expenses involved in the postgraduate medical education of physicians which the Medicare program has historically recognized as worthy of support under the reimbursement system.
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> The adjustment for indirect medical education costs is only a proxy to account for a number of factors which may legitimately increase costs in teaching institutions.

H.R. Rep. No. 98-25(I)(1983), reprinted in 1983 U.S.C.C.A.N. 219, 359.

Although increased operating costs in teaching hospitals (apart from the direct costs of the graduate medical education) were therefore recognized as indisputable facts, the problem was that these increased costs could not be quantitatively isolated because they are not direct costs that can be ascertained from the hospital's records. In an effort to nevertheless compensate teaching hospitals for these indirect medical education costs, Congress concluded that the greater the "teaching intensity" in a residency program the greater the indirect costs of such a program, and hence the greater the reimbursement should be. The "teaching intensity," as noted earlier, is measured by the ratio of the teaching hospital's full-time equivalent residents to the hospital's beds in the statutory formula adopted by Congress.

While it is true that the purpose of the IME adjustment is to reimburse teaching hospitals for the largely unmeasurable increased operating costs of a teaching hospital, there is nothing in the statute, or in the statutory formula for estimating those costs, to indicate that Congress considered only the costs attributable to residents providing direct care and treatment of the hospital's patients (only one of the activities involved in a required residency program) as causing the indirect increase in the hospital's operating costs.

It is obvious that among the cited examples requiring the IME adjustment are increased patient care costs attributable to a resident directly caring for a patient, *e.g.*, additional tests and procedures ordered by a resident that more experienced physicians would not require. It is equally obvious, however, that the IME adjustment includes increased operating costs that are ***not*** attributable to a resident directly caring for a particular patient. Included are increased costs

[7] In regulations dealing with payments for the services of physicians in teaching settings, §415.152 contains a definition of "Direct medical and surgical services" as "services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital making the cost election described in §§415.160 through 415.162." If the purpose of the 2001 amendment was simply to clarify the Secretary's long-standing policy to disallow a resident's time not spent on direct patient care, it would seem that the Secretary, instead of carving out a single activity—research—could have easily promulgated an amendment to §412.105(f)(iii) which would simply have provided that "the time spent by a resident that is not spent on direct medical and surgical services to individual beneficiaries is not countable." This, of course, was not done.

due to the "*severity of illness of patients* requiring the specialized services and treatment programs provided by teaching institutions" which are *in addition to* "the additional costs *associated with the teaching of residents*." Even the additional costs associated with the teaching of residents include "the extra demands placed *on other staff* as they participate in the education process." It is also important to note that the specific examples of increased costs mentioned in the report are not the only factors that justified the IME reimbursement. As the House Report stated, there are "a *number of factors* which may legitimately increase costs in teaching institutions." (emphasis added).

The point is that indirect medical education costs are virtually impossible to quantify in that they include not only costs directly caused by residents in actually caring for and treating patients, but also costs indirectly caused by the very nature of teaching hospitals. Regardless of the nature of the costs, they are measured by a Congressional formula that is a "proxy," or substitute, for any attempt to itemize and quantify such costs—a formula that makes no distinction as to the nature of the costs incurred. Reimbursement is not based on time spent at the bedside of patients, time spent on making rounds, time spent on ordering tests, time spent on record keeping or on any other aspect of patient care. Instead, reimbursement is based on the degree of *teaching intensity* as measured by a formula that is based on the ratio of the number of residents to the number of beds. The higher that ratio, the greater the teaching intensity; and a greater teaching intensity equates with greater indirect costs of that teaching. This is simply a method of approximating *all types* of increased indirect costs incurred by teaching hospitals, arising not only from costs attributable to direct patient care by residents, but also from increased general costs attributable to engaging in teaching activities and treating patients with more severe illnesses than are normally encountered in non-teaching hospitals.

In short, there is nothing in the purpose of the IME statute, or in its statutory formula, that shows any intention of Congress to base reimbursement on a method that excludes all required residency program activities from consideration except those considered by the Secretary to involve a resident providing direct care to a specific patient.

2. The Secretary's Interpretation of "Indirect Costs of Medical Education"

As noted earlier, the Secretary's argument is that adding the challenged requirement to the language of the regulation is justified by the Secretary's previous interpretation of the phrase "indirect costs of medical education" in 42 U.S.C. § 1395ww(d)(5)(B)[8] To that end, the Secretary argues:

> In promulgating regulations implementing 42 U.S.C. § 1395ww(d)(5)(B), the statute authorizing IME payments, the Secretary has, over the past nearly 20 years, repeatedly interpreted IME payments as being for the higher cost of patient care at teaching hospitals. For example, in a final interim rule issued on May 6, 1986, the Secretary stated
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> indirect costs of medical education incurred by teaching hospitals are the increased operating costs (that is, patient care costs) that are associated with approved intern and resident programs. These increased costs may reflect a number of factors; for example, an increase in the number of tests and procedures ordered by interns and residents relative to the number ordered by more experienced physicians or the need of hospitals with teaching programs to maintain more detailed medical records.
>
> 51 Fed. Reg. at 16775. Likewise, in a final rule issued September 29, 1989, the Secretary stated that
>
> As used in section 1886(d)(5)(B) of the Act, "indirect costs of medical education" means those additional operating (that is, patient care) costs incurred by hospitals with graduate medical education programs. The indirect costs of medical education might, for example include added costs resulting from an increased number of tests ordered by residents as compared to the number of tests normally ordered by more experienced physicians."
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> 54 Fed. Reg. at 40286.[9]

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[8] 42 U.S.C. § 1395ww(d)(5)(B) in its entirety reads as follows:

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2) of this section, except as follows:

(i) The amount of such additional payment shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii) and the amount paid to the hospital under subparagraph (A), by (II) the indirect teaching adjustment factor described in clause (ii).

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor for discharges occurring on or after May 1, 1986, is equal to 1.89 × (((1 + r) to the nth power) − 1), where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals .405.

(iii) In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.

(iv) In determining such adjustment, the Secretary shall continue to count interns and residents assigned to outpatient services of the hospital as part of the calculation of the full-time-equivalent number of interns and residents.

[9] Although not cited by the Secretary, a more recent discussion by the Secretary dealing with the purpose of IME costs is found in 55 Fed. Reg. at 19457 in which the Secretary does not describe increased operating costs as "patient care costs" as

(Def.'s Mem. in Support Def.'s Mot. for Summ. J. at 14).

It is undisputed that an increase in operating costs associated with teaching hospitals was the reason for the IME reimbursement.[10] The Secretary, however, equates "increased operating costs" with "patient care costs" and then gives as examples of patient care costs *only* (1) an increase in the number of tests and procedures ordered by interns and residents, and (2) the need for hospitals with teaching programs to maintain more detailed records. As noted above, however, the IME adjustment is *not* based solely on these factors. It is also based on factors that are *not* attributable to a resident ordering more tests than an experienced physician or the need for more detailed records. It is also based on other factors described in the House Report that do not necessarily involve residents directly rendering care to the hospital's patients, *e.g.*, the severity of the illnesses of patients who seek the specialized services and treatment programs available in teaching hospitals, and the general costs associated with the teaching of residents, including extra demands placed on the medical staff.

It is precisely because the indirect costs *cannot* be adequately itemized and quantified that Congress devised a formula based on the degree of teaching intensity in a particular hospital, as a substitution for any other method of reimbursing such costs. If Congress had believed that the indirect medical education costs of a teaching hospital could be separately identified and quantified, and that higher direct patient care costs could be so determined from the hospital's records, then Congress could easily have qualified its formula for reimbursement to restrict the number of FTE residents to a number based only on hours that residents spent providing "patient care." It obviously did not do so.[11]

The Secretary also contends that the agency's regulations concerning a determination of the number of FTE residents show that there is a different method used for IME payments and GME payments and that this difference is "consistent with the respective purposes of the payments." (Def.'s Mem. in Support of Def.'s Mot. for Summ. J. at 6).

Prior to the adoption of the regulation at issue in this case, there was a radically different methodology used. The FTE resident count for IME purposes was based simply on the number of residents assigned to the hospital and providing services there on September 1. The FTE count of residents for GME purposes was based on the total time necessary to fill a residency slot. The Secretary decided that "the GME and IME counts should be consistent. Therefore, in §412.118, we would revise the current one-day method for counting interns and residents for purposes of computing the IME adjustment to a method more consistent with that used for computing GME payments under §413.86." 55 Fed. Reg. 19426, 19457. The current difference in the methodologies, the one which is emphasized by the Secretary, is that for IME purposes a resident who does not work full time in an area of the hospital that is subject to the prospective payment system or the outpatient department of the hospital is counted as a partial FTE based on the proportion of time assigned to one of those areas compared to the total time necessary to fill a full-time residency slot. That limitation does not apply to the residency count for GME purposes.

While this difference in the regulations does exist, it does little, if anything, to support the Secretary's position in this case. The entire IME program was created in order to adequately compensate teaching hospitals when the reasonable cost system was changed to the prospective payment system. Because reimbursement amounts under the prospective payment system were fixed amounts that do not distinguish between teaching and non-teaching hospitals, IME payments were added to the PPS income received by a teaching hospital, because it was recognized that the PPS did not account for the *indirect* costs of having a medical education program. If residents are *not* assigned to the portion of the hospital subject to the prospective payment system or the outpatient department, then it makes sense to not supplement the hospital's PPS income with any indirect medical education costs. The difference between assigned and non-assigned areas has nothing to do, however, with the Secretary's attempt in this case to draw distinctions among the *types of activities* required of a resident who *is assigned* to an area of the hospital subject to the prospective

(Footnote Continued)

he does in the references cited by the Secretary in his memorandum: 51 Fed. Reg. at 16775 and 54 Fed. Reg. at 40286. In 1990, in 55 Fed. Reg. at 19457, the Secretary said, "[a]s noted above, the IME payment is an add-on to a teaching hospital's total DRG payment and is intended to compensate for the additional operating costs (that is, indirect costs) incurred by the hospital in training interns and residents." The Secretary here, correctly, does not equate "operating costs" with "patient care costs."

[10] Riverside so admits. "Increased operating costs incurred by teaching hospitals was the reason for the additional IME payment, but it does not follow . . . that a hospital demonstrate how each medical education activity affected the care of a particular patient." (Pl.'s Reply and Mem. Contra Def.'s Mot. for Summ. J. at 8).

[11] It could be very difficult to define exactly what is included in the Secretary's phrase "patient care costs." For example, if a resident suspects that a patient has a mental disorder, and does some research in order to better understand the patient's condition and treatment, is this time spent for "patient care"? If the same resident, for the same purpose, attends a psychiatric seminar, is this time spent for "patient care"? The Secretary, in the present case, disallowed time spent in psychiatric seminars.

payment system or the outpatient department of the hospital.

The Secretary further contends that any resident time that is not directly related to patient care—using as an example, research—should be excluded "because the hospital does not incur any indirect cost, that is higher patient care costs, from the residents involved in research because they are not ordering additional tests and procedures for patients." (Def.'s Mem. in Support Def.'s Mot. for Summ. J. at 16-17). The problem with the Secretary's argument is the same problem described at length earlier in this opinion. Contrary to the purpose of IME and the Congressional reasons for enactment of the program, the Secretary persists in focusing on a single, isolated factor that can increase the costs of a teaching hospital—namely the ordering of additional tests by residents that a more experienced physician would probably not need. As pointed out earlier, however, this factor has been mentioned as simply one, but clearly not the only, example of a number of elusive factors that increase the operating costs of a teaching hospital over and above the quantifiable direct costs of a teaching program.

The Secretary also contends that because Riverside would be reimbursed for its direct costs of medical education, it should not be compensated for expenses attributable to costs of journal club and the seminars at issue in this case, because this would be, in the Secretary's words, an "attempt to have Medicare pay again." (Def.'s Mem. in Support Def.'s Mot. for Summ. J. at 19). If the IME program were based on reimbursement for the actual cost of each individual activity included in a resident's required program, the Secretary's argument might have some validity. However, that is not the basis of the IME program. It is precisely because the *indirect* costs of medical education *cannot* be so measured that Congress developed a formula, which is *not* based on the specific nature of each resident activity or the cost of each activity, but rather is based on the intensity of the entire accredited teaching program, a program that requires various types of teaching and learning experiences. To the extent the Secretary believes that some aspect of that program should not be counted and the time excluded, the recourse is to promulgate an amendment to the regulations, and not to impose this exclusion without compliance with the Administrative Procedure Act.

Finally, the Secretary argues that the regulation must be considered in the context of all PPS regulations and the entire Medicare regulatory scheme. (Def.'s Mem. in Support Def.'s Mot. for Summ. J. at 18). The court has no problem with this argument, but it does not support the Secretary's conclusion. First, the regulation in question is, as noted earlier, in very plain language; it is not in the slightest ambiguous or in any need of interpretation by anyone. Second, even if an interpretation were needed, which is not true, it is clear that the Secretary's "interpretation" of the regulation is not required by the Congressional purpose for the IME program and the statutory formula Congress developed based on the "teaching intensity" of a particular hospital's residency program. Third, to insert the additional requirement desired by the Secretary would require the Secretary to comply with the procedures mandated by the Administrative Procedure Act for the further amendment of the regulation in question. It cannot be done under the guise of an "interpretation."

IV. Conclusion

The court finds, for the reasons stated herein, that the Secretary's position in this case is contrary to both the plain language of the applicable regulation and the methodology adopted by Congress for the reimbursement of the indirect costs of medical education provided by teaching hospitals. Accordingly, the decision of the Secretary is **REVERSED**, and the case is hereby **REMANDED** to the Provider Reimbursement Review Board for a determination of the appropriate amount of reimbursement, together with interest thereon as provided by 42 U.S.C. § 1395oo(f)(2), and for further proceedings consistent with this opinion.

IT IS SO ORDERED.

¶301,342 Rush-Presbyterian-St. Luke's Medical Center v. Thompson.

U.S. District Court for the Northern District of Illinois, No. 02 C 5375, Aug. 22, 2003.

Medicare: Prospective Payment Systems

Prospective payment systems—Inpatient hospitals—Outliers.—CMS is not required to retroactively adjust outlier payments under the inpatient hospital prospective payment system (PPS) if actual payments do not match the outlier thresholds set by CMS. Under CMS' interpretation of the statutory language concerning outlier payments, CMS must prospectively establish the outlier thresholds at levels *likely to result* in outlier payments between five and six percent of the projected DRG prospective payments for that year, and any shortages need not be reimbursed. The hospital that filed suit argued that the statutory language requires that *actual* outlier payments for a given year fall within the five to six percent range of the DRG prospective payments for that year, and that any shortages must be retroactively reimbursed. The meaning of the statutory text, however, is ambiguous. CMS' interpretation was a permissible construction of the statutory language because (1) CMS' interpretation had been consistent over the entire duration of the inpatient hospital PPS; (2) retroactive reimbursement is

